**FOREWORD** 

**INTRODUCTION** 

O-CRESOL CAS N°: 95-48-7

# SIDS INITIAL ASSESSMENT PROFILE

CAS Nr.	95-48-7
Chemical Name	o-Cresol
Structural formula	ОН

# RECOMMENDATION OF THE SPONSOR COUNTRY

further work is required

# SHORT SUMMARY WHICH SUPPORTS THE REASONS FOR THE RECOMMENDATIONS

The worldwide production volume of o-cresol is approx. 37 000 - 38 000 t/a. It is mostly used as an intermediate for the production of pesticides, epoxy resins, dyes and pharmaceuticals, but also as a component of disinfectants and cleaning agents. o-Cresol is "readily biodegradable" and has a low bio- or geoaccumulation potential. The most sensitive environmental species to o-cresol are salmonid fish (96h-LC50 = 6.2 - 8.4 mg/l). The derived PNEC, based on (Q)SARs for chronic effects is  $12 \mu \text{g/l}$ .

For toxicological endpoints, the NOAEL for repeated dose (90d - study) was 50 mg/kg bw/d for mice and rats. For reproductive toxicity, no increased risks to offspring were observed in the absence of parental effects. The NOAEL for parental toxicity was determined as 30 mg/kg bw/d in rats. o-Cresol can induce chromosomal aberrations and increase SCEs *in vitro* but not *in vivo*. There are no adequate bioassays or chronic studies available to assess the carcinogenic potential of o-cresol. There are indications though for a tumor promoting activity.

Aquatic PECs of up to  $168.6 \mu g/l$  were estimated for the use as an intermediate and as a component in different products. Human doses of up to 1.74 mg/kg bw/d are estimated from exposures of workers using products containing o-cresol. There are no consumers exposed to o-cresol containing products.

For the environment, based on the known facts and properties, a risk to the aquatic compartment has to be assumed. For workers, the 'margin of safety' between the NOAEL from laboratory studies and the estimated exposure is very low, and a risk has to be assumed.

## IF FURTHER WORK IS RECOMMENDED, SUMMARISE ITS NATURE

The aquatic PNEC is based on (Q)SAR estimations for the long-term effects upon fish. In a first step, this (Q)SAR-value should be verified by conducting a 60 day early life stage test with *Oncorhynchus mykiss*. Studies on chronic toxicity and carcinogenicty should be conducted. In the mean time, in case the 'margins of safety' cannot be raised by better exposure estimates at the workplace, protective measures should be taken:

- a reduction of the limit concentration at the workplace (8-h time weighted average, TWA), at present 5 ppm (22 mg/m<sup>3</sup>), should be considered;
- the threshold specific concentration of o-cresol in preparations requiring warning labelling should be reduced (classification and labelling according to EU legislation);
- because of the increasing tendency for substitution, the use of o-cresol in consumer products should be reviewed

# **SIDS SUMMARY**

# o-Cresol

CAS-NO	).: 95-48-7		PROTOCOL	RESULTS
PHYSIC	CAL CHEMICAL			
2.1	Melting-Point	<u> </u>	NA	31 °C
2.2	Boiling-Point		NA	191 °C (at101.3 kPa)
2.3	Density		NA	ca. 1046 kg/m <sup>3</sup>
2.4	Vapour Pressure		NA	24 Pa at 25 °C
2.5	Partition Coefficient (Log Pow)		exp.	2.2
2.6 A	Water solubility		NA	26 g/l at 20 °C
В	pН		/	At °C
	pKa		/	/
2.12	Oxidation: Reduction potential		/	mV
	ONMENTAL FATE / GRADATION			
3.1.1	Photodegradation		exp. (Atkinson)	In air $T_{1/2} = 9.6$ hours
3.1.2	Stability in water		autooxidation	$T_{1/2} > 1$ year
3.2	Monitoring data			In air = $0.05 - 40 \mu g/m^3$ In surface water = n.d. $-68 \mu g/l$ In soil / sediment = $/ \mu g/g$ In biota = $/ \mu g/g$
3.5	Biodegradation		analoguous to OECD 301	86 % after 20 days
ECOTO	XICOLOGY			
4.1	acute/prolonged toxicity to fish	Oncorhynchus mykiss	US-EPA 1974	$LC_{50}$ (96 hr) = 8.4 mg/l
		Salmo trutta	NA	$LC_{50}$ (96 hr) = 6.2 mg/l
4.2	acute/prolonged toxicity to aquatic invertebrates ( daphnia )	Daphnia magna	NA	$EC_{50}$ (48 hr) = 9.2 - 23.5 mg/l
4.3	toxicity to aquatic plants e. g. algae	Scenedesmus quadricauda	NA	NOEC (8 d) = 11 mg/l
		Microcystis aeruginosa	NA	NOEC $(8 \text{ d}) = 6.8 \text{ mg/l}$
4.4	toxicity to microorganisms	Pseudomonas putida	NA	NOEC $(16 \text{ h}) = 33 \text{ mg/l}$
4.5.1	chronic toxicity to fish			
4.6.1	toxicity to soil dwelling organisms			
4.6.2	toxicity to terrestrial plants			

CAS-N	NO.: 95-48-7 SPECIES PROTOCOL RESULT		RESULTS	
TOXIC	OLOGY			
5.1.1	acute oral toxicity	rat rabbit mouse	NA NA NA	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
5.1.2	acute inhalation toxicity	rat rabbit mouse	NA NA NA	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
5.1.3	acute dermal toxicity	rabbit rat	NA NA	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
5.4	repeated dose toxicity	rat rat mouse	inhal.; 4-6h/d; 5d/wk, 16 wk exp; oral; 13wk oral; 13wk	NOAEL = <9 mg/m <sup>3</sup> NOAEL = 50 mg/kg bw/d NOAEL = 199-237 mg/kg bw/d
5.5	genetic toxicity in vitro			
	bacterial test (gen mutation)		Ames	- (with and without metabolic activation)
	non bacterial in vitro test	mice lymphoma	NA	-(with and without metabolic activation)
		rat hepatocytes	DNA repair	negative
		Drosphilia melanogaster	sex-linked recessive mutations	negative
		CHO cells	chromosomal aberr.	positive
		CHO cells	SCE	positive
5.6	genetic toxicity in vivo	mouse	induction of micronuclei in blood erythrocytes	negative
		mouse	SCE in bone marrow, lung or Liver	negative
		mouse	dominant lethal	negative
5.8	toxicity to reproduction	rat	oral, 5d/w, 10w	
		mink	oral, 8w	NOAEL = 108-190 mg/kg (F1) NOAEL = 24 - 40 mg/kg (P)
5.9	developmental toxicity / teratogenicity	rat	oral; gd 6 - 19	NOEL (maternal) = 175 mg/kg NOEL (develomental) = 175mg/kg
		rabbit	oral; gd 6 - 18	NOEL (maternal) = 5 mg/kg NOEL (develomental) = 50 mg/kg
5.11	experience with human exposure			

#### 1. GENERAL SUBSTANCE INFORMATION

#### **Identification of the substance**

CAS-Nr: 95-48-7 Name o-Cresol

Common synonyms Phenol, 2-methyl

1-Hydroxy-2-methylbenzene

2-Hydroxytoluene o-Cresylic acid o-Hydroxytoluene o-Methylphenol o-Oxytoluene 2-Methylphenol

o-Methylphenylol

o-Toluol

2-Cresol

Molecular formula: C<sub>7</sub>H<sub>8</sub>O

Structural formula:

#### Purities/impurities, additives

Purity of industrial product : > 98.5 %

Identity of major impurities: Phenol, m-Cresol, p-Cresol & 2,6-xylenol

Additives: None

Commercial cresol, also known as cresylic acid or tricresol, contains all three isomers (o,m,p) with small amounts of phenol and xylenols. Technical grade cresol available in the USA contains about 20% ocresol, 40% m-cresol, 30% p-cresol and 10% phenol and xylenols (Deichmann & Keplinger, 1981).

#### **Physico-chemical properties**

Physical state: solid at 20 € and 101.3 kPa

Melting point: 31  $\mathbb C$  Boiling point: 191  $\mathbb C$ 

Density: 1046.5 kg/m³ Vapour pressure: 24 Pa at 20  $\mathbb C$  Water solubility: 26 g/l at 25  $\mathbb C$  n-octanol/water partition coefficient (log10): 1.95 - 2.17

Note: not much data is available on the test conditions for either the results obtained by the shake flask method (logPow = 1.95) or by the HPLC method (logPow = 2.17). These values seem nevertheless to confirm each other and are further validated by the estimated value of 2.00. In the following, a value of logPow = 2.00 will be used.

Flash point: 81 °C

Lower explosive limit:

1.3 % by vol.

#### 2. GENERAL INFORMATION ON EXPOSURE

## **Production / consumption :**

### Production levels:

According to Srour (1989), the total world production was 37 000 - 38 000 tons in 1987, with

respectively: W. Europe : 18 000 t

USA : 13 000 t Japan : 5 000 t

The estimated consumption levels for 1992 are:

W. Europe : 21 000 t USA : 5 800 t Japan : 9 350 t

### <u>Production processes:</u>

Approximately 60 % of o-cresol is derived from coal tar and crude oil by using classical techniques such as distillation, stripping, liquid-liquid extraction. About 40 % is obtained synthetically by alkylation of phenol with methanol, either in the vapour or liquid phase:

## Methylation in vapour phase:

An overheated mixture of phenol and methanol flows on a catalyst in a multitubular reactor at 300-460  $\mathbb C$ . The heat of reaction can be used for high pressure steam production. The secondary products (CO, CO<sub>2</sub>, H<sub>2</sub> and CH<sub>4</sub>) are used as fuel to heat the phenol/methanol mixture. The catalysts most often used are magnesium oxide and alumine. The yield of synthesis varies from 60 to 85%, depending on catalyst and temperature.

### Methylation in liquid phase:

The reaction is conducted in the presence of alumina, at 300°C and at 35 atmospheres of pressure. The yields of synthesis are nearly the same as those from the vapour phase. Aluminium methylate can also be used as catalyst.

Alcaline hydrolysis of chlorotoluene mixtures, and occasionnally of o-chlorotoluene have also been used as a production route and o-cresol is also a by-product in the synthesis of 2,6-xylenol .

#### Uses:

In 90% of the uses, cresols are organic intermediates in manufacturing of :

- phenolic and epoxy resins and plasticizers (phosphate esters);
- herbicides (dinitrocresols, MCPA, MCPP);
- rubber and plastic antioxidants;
- dyes;
- deodorizing and odor-enhancing compounds, fragrances;
- pharmaceuticals.

Additional industrial uses of o-cresol or mixtures of cresols are as follows:

• antiseptics and disinfectants;

• cleaning compounds, degreasers, automotive cleaners (concentration in a cleaning product of car carburetttors : 0,3 % (Product Register, Finland));

- solvent, paint strippers and paints;
- adhesive and connected products; sealing adhesive masses (0,3 2 % w), adhesive (< 1% w (Product Register, Finland));
- additive to phenol-formaldehyde resins;
- fiber treatment, wood preservatives;
- photography;
- ore flotation agent;
- retarding product in cold-box forgery method (Product Register, Finland);
- cutting oils.

Cresols (ortho, meta, para) in preparations are usually present at very low concentration.

Cresols are not found in any end-use consumer products in the United States. According to IPCS, there are still some consumer products: cresols (<u>isomer not defined</u>) may be used as desinfectants in some soaps and as wood preservatives. In France, it is not possible to affirm that all consumer uses have stopped but information from anti-poison centers show a tendency for o-cresol to disappear from these products (Product Register, France).

The end-use breakdown for Western Europe is estimated by Srour (1989) for 1992 as follows:

Use in Western Europe	Quantity (tons)
p-Chloro-o-cresol	16 000
Epoxy novolacs	1 400
o-Cresotinic acid	1 075
DNOC (insecticide)	775
Tert-butyl-o-cresol	1 200
Others	550

# **Emission pattern**

Releases of o-cresol into the environment might occur during/with:

- any operations involving handling and use of petroleum substances, o-cresol being a natural component of crude oil;
- production of cresols or pure o-cresol;
- use of o-cresol as a chemical intermediate;
- formulation and use of o-cresol containing products (e.g. disinfectants, cleaning agents, adhesives etc.)
- exhaust of vehicules powered with petroleum-based fuels as well as other combustion processes;

According to the US Toxic Release Inventory (US-EPA, 1995a), releases of o-cresol were reported from 22 industrial producers or users in 1993. The total released or transferred quantities are:

Emissions	Quantities (tons)
fugitive or nonpoint air emissions	5.987
stack or point air emissions	69.853
surface water discharges	0.072
underground injection	254.016
releases to land	0.055

transfer to POTW	18.578
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#### 3. ENVIRONMENT

# 3.1 Exposure assessment

#### 3.1.0 General discussion

## **Degradation**

#### Hydrolysis

No test on hydrolysis with o-cresol was performed. Based on the molecular structure of o-cresol, hydrolysis is not expected to be an important fate process. The half-life for autooxidation in water at 25  $\mathbb{C}$  was determined to be 462 days (Mohsen Moussavi, 1979).

#### **Biodegradation**

No results from standard tests on ready biodegradation are available. The test system and test conditions used by Buzzell et al. (1968) are nevertheless similar to those prescribed by the OECD 301 guidelines (e.g. high substance/inoculum ratio, non adapted inoculum). Several other non-standard test results confirm the tendency for rapid biodegradation. o-Cresol can therefore be considered as readily biodegradable.

As no results from biodegradation simulation tests in STPs, in surface water or in soil are available, the degradation rates have to be estimated based on the "ready biodegradability" classification and partition behaviour of o-cresol. According to the method described in the EU-Technical Guidance Documents (CEC, 1996), the following biodegradation rate constants can be derived:

compartment / medium	biodegradation rate
activated sludge (STP)	$k_{\text{STP}} = 1 \text{ h}^{-1}$
surface water	$k_{SW} = 0.047 \text{ d}^{-1}$
sediment	$k_{sed} = 0.002 d^{-1}$
soil	$k_{soil} = 0.023 d^{-1}$

# **Photooxidation**

In the atmosphere, o-cresol will react with the photochemically produced hydroxyl radicals. Based upon atmospheric concentrations of  $5 \cdot 10^5 \cdot \text{OH/cm}^3$  the atmospheric half-life of o-cresol has been estimated to be 9.6 hours (Atkinson, 1985). During the night, higher degradation rates with NO<sub>3</sub> radicals are expected (Howard, 1989).

In the presence of humic acids, indirect photolysis in water is to be expected. In a polluted eutrophic Swiss lake that contained a dissolved organic matter concentration of 3.1 mg/l, the estimated natural half-life for o-cresol in the top meter concentration as a result of exposure to June sunlight was 11 days (Faust & Hoigné 1987).

#### **Distribution**

Based on the water solubility of 26000 mg/l and the vapour pressure of 24 Pa at 20  $\mathbb{C}$ , a Henry's law constant H = 0.1 Pa·m<sup>3</sup>/mol can be estimated, suggesting that o-cresol is not very volatile from water.

A measured Koc-value of 22 l/kg is available (Boyd, 1982). Based on the Koc of 22 l/kg, the partition coefficients in the different compartments can be estimated using default organic carbon contents in the different compartments:

compartment	OC content in solid phase	partition coefficient
soil-water	2 %	$K_{p\_soil} = 0.44 \text{ l/kg}$
sediment - water	5 %	$K_{p\_sed} = 1.1 \text{ l/kg}$
suspended matter - water	10 %	$K_{p\_susp} = 2.2 \text{ l/kg}$

#### Elimination in WWTPs

Based on the above cited physical chemical properties (log H = -1;  $logP_{ow} = 2$ ), as well as the biodegradation rate of 1  $h^{-1}$  in STP, the elimination through biodegradation and distribution can be estimated with the model SIMPLETREAT:

% to air	0
% to water	9
% to sludge	0
% degraded	91
% removal	91

#### Accumulation

A bioaccumulation test with *Brachydanio rerio* according to OECD GL 305 E yielded a BCF of 10.7 (Butte et al., 1987). The potential of o-cresol for biomagnification with the food chain can be considered as low.

## 3.1.1 Aquatic compartment (incl. sediment)

PEC-estimations need to be performed for the following life-stages and uses:

- production
- use of o-cresol as a chemical intermediate;
- formulation of o-cresol containing products (e.g. disinfectants, cleaning agents, adhesives etc.);
- use of these products.

#### 3.1.1.1 Production

The highest single-plant production capacity for o-cresol is reported by Srour (1989) to be 15000 t/a. The following exposure scenario, as proposed in CEC (1996), can be used for the PEC-estimation:

Production volume: 15000 t/a

Release fraction to waste water: 0.3%

Duration of release: 300 d/a

Elimination in the STP: 91% (cf. above)

Flow of receiving river: 60 m<sup>3</sup>/s

A concentration in the receiving water body of  $PEC_{local} = 2.6 \mu g/l$  can be derived.

The above scenario was derived from data provided by the European chemicals industry. It is not clear whether this scenario also applies to the petroleum industries. Monitoring data from waste water due to petroleum refining activities are available though (Shackelford et al., 1983) which could be used. o-cresol was detected in 10 samples, with a median concentration of 123.5 g/l and a maximum concentration of 10100 g/l. The dilution of these waste waters in the receiving water bodies is not known. A default dilution of 10 can be assumed for the PEC calculation. The median surface water concentration would therefore be  $PEC_{local} = 12.3 \mu g/l$  (maximum: 1010 g/l).

Furthermore, the concentration of o-cresol was determined in the waste water of one of the major European producers of o-cresol. All measurements indicated a concentration below 5 g/l in the untreated waste water (personal communication, no further data available). Assuming an elimination of 91% in the STP and a dilution of 10 in the receiving water body, a **PEC**<sub>local</sub> of 0.05  $\mu$ g/l can be estimated.

#### 3.1.1.2 Use as a chemical intermediate

Western Europe is the highest consumer of o-cresol. The highest single customer consumption in Europe is reported by Srour (1989) to be 4500 t/a. The following exposure scenario, as proposed in CEC (1996), can be used for the PEC-estimation:

Volume: 4500 t/a

Release fraction to waste water: 0.7%

Duration of release: 300 d/a

Elimination in the STP: 91% (cf. above)

Flow of receiving river: 60 m<sup>3</sup>/s

A concentration in the receiving water body of  $PEC_{local} = 1.8 \,\mu g/l$  can be derived. Furthermore, several results from analytical monitoring of waste waters from chemical conversion industries are available (Shackelford et al., 1983). Using a default dilution of 10 in the receiving water bodies, the following surface water concentrations can be derived:

industrial activity	freq. of occurence	median conc. [μg/l]	PEC <sub>local</sub> [µg/l]
organics and plastics	24	503.5	50.3
plastics and synthetics	1	1685.9	168.6
pharmaceuticals	7	83.3	8.3
organic chemicals	11	1217.3	121.7

The PECs based on analytical measurements of waste waters are significantly higher than the PEC calculated by a default scenario. This is mainly due to the discrepancy of the estimated dilution factor in these two approaches.

## 3.1.1.3 Formulation of o-cresol containing products

As shown above, most of the consumed o-cresol in Western Europe is used as a chemical intermediate. The remaining 550 t/a are probably used in the formulation of products e.g. disinfectants, cleaning agents, adhesives etc. Due to the wide spectrum of use, the use of 10% i.e. 55 t/a at a single site for formulations of products can be considered as a worst case. The following exposure scenario, as proposed in CEC (1996), can be used for the PEC-estimation:

Quantity used at a single site: 55 t/a Release fraction to waste water: 2%

Duration of release: 300 d/a

Size of the STP receiving the waste water:  $2000 \text{ m}^3/\text{d}$ 

Elimination in the STP: 91% (cf. above) Dilution in the receiving water body: 10

A concentration in the receiving water body of  $PEC_{local} = 16.5 \,\mu g/l$  can be derived. Furthermore, several results from analytical monitoring of waste waters from industries producing o-cresol-containing products are available (Shackelford et al., 1983). Using a default dilution of 10 in the receiving water bodies, the following surface water concentrations can be derived:

industrial activity	freq. of occurence	median conc. [µg/l]	PEC <sub>local</sub> [μg/l]
paint and ink	1	30.9	3.1
soaps and detergents	2	44.2	4.4
synfuels	2	290.2	29.0

The PECs based on analytical measurements of waste waters are very close to the PEC calculated by a default scenario.

## 3.1.1.4 Use of o-cresol containing products

As the exact quantities consumed for the different applications are not known, no realistic exposure scenarios can be derived. Many results from analytical monitoring of waste waters from industries using o-cresol-containing products are available (Shackelford et al., 1983). Using a default dilution of 10 in the receiving water bodies, the following surface water concentrations can be derived:

industrial activity	freq. of occurence	median conc. [μg/l]	PEC <sub>local</sub> [μg/l]
timber products	14	105.5	10.5
printing and publishing	4	11.4	1.1
non-ferrous metals	5	36.4	3.6
textile mills	4	72.5	7.2
pulp and paper	4	59.9	6.0
rubber processing	7	435.3	43.5
auto and other laundries	3	460.9	46.1
gum and wood industr.	4	3.3	0.3
aluminum	4	2.4	0.2
electronics	5	237.5	23.7
electroplating	2	4.8	0.5
oil and gas extraction	10	4.1	0.4

# 3.1.1.5 Monitoring data

In the STORET data base (US-EPA, 1993) surface water concentrations are reported (315 samples), ranging from below detection limit to 68 g/l, with a mean concentration of 10.9 g/l. The 90-percentile value, which would be most relevant for the risk assessment is not available. The mean concentration of 10.9 g/l is nevertheless in agreement with the above estimated concentrations.

## 3.1.2 Atmosphere

In parallel to the estimations for surface water concentrations, the local air concentrations and wet and dry depositions onto soil can be estimated for the different life-stages of o-cresol.

NOTE: the contribution of the amount stripped in the WWTP is low and is therefore neglected in the estimations below.

#### 3.1.2.1 Production

The highest single-plant production capacity for o-cresol is reported by Srour (1989) to be 15000 t/a. The following exposure scenario, as proposed in CEC (1996), can be used for the PEC-estimation:

Production volume: 15000 t/a

Release fraction to air: 0.01% (default)

Duration of release: 300 d/a = >Daily release rate: 5 kg/d

As proposed in CEC (1996), the model OPS can be used to estimate the air concentration at a distance of 100 m from the source. For a source strength of 1 kg/d, a concentration of 0.278 g/m<sup>3</sup> was derived, so that with the above estimated release rate of 5 kg/d: **PEC**  $_{local\ air} = 1.4\ \mu g/m^3$ .

The average deposition over a radius of 1 km around the source can also be estimated. The deposition flux is dependent on the fraction of the chemical that is associated with the aerosols:

$$DEP_{total} = Emission \cdot [FR_{aerosol} \cdot Dstd_{aer} + (1 - FR_{aerosol}) \cdot Dstd_{gas}]$$

with:

 $DEP_{total}$  = total deposition flux [kg.m<sup>-2</sup>.d<sup>-1</sup>]

FR<sub>aerosol</sub> = fraction of the chemical bound to aerosol [-]

Dstd<sub>aer</sub> = standard deposition flux of aerosol bound compounds at source strength

of 1 kg/d (=  $1 \cdot 10^{-8}$  kg.m<sup>-2</sup>.d<sup>-1</sup>)

Dstd<sub>gas</sub> = standard deposition flux of gaseous compounds as a function of the

The fraction of the chemical associated with aerosol particles can be estimated on the basis of the chemical's vapour pressure, according to Junge (described in CEC, 1996):

$$FR_{aerosol} = \begin{array}{c} CON_{junge} \cdot SURF_{aer} \\ \\ VP + CON_{junge} \cdot SURF_{aer} \end{array}$$

with:

CON<sub>iunge</sub> constant of Junge-equation [Pa.m]

SURF<sub>aer</sub> surface area of aerosol particles [m<sup>2</sup>.m<sup>-3</sup>] VP vapour pressure [Pa] (here 25000 Pa)

As a default, the product of  $CON_{iunge}$  and  $SURF_{aer}$  is set to  $10^{-4}$  Pa (1).

$$\Rightarrow$$
 DEP<sub>total</sub> = 2.0·10<sup>-9</sup> kg.m<sup>-2</sup>.d<sup>-1</sup>

#### 3.1.2.2 Use as a chemical intermediate

Western Europe is the highest consumer of o-cresol. The highest single customer consumption in Europe is reported by Srour (1989) to be 4500 t/a. The following exposure scenario, as proposed in CEC (1996), can be used for the PEC-estimation:

Volume: 4500 t/a

Release fraction to air: 0.1% Duration of release: 300 d/a => daily release rate: 15 kg/d

A concentration at a distance of 100 m from the source of  $PEC_{local\_air} = 4.17 \ \mu g/m^3$  and an average deposition rate of  $DEP_{total} = 6.0 \cdot 10^{-9} \ kg.m^{-2}.d^{-1}$  can be derived by the method described above.

#### 3.1.2.3 Formulation of o-cresol containing products

The use of 55 t/a at a single site for formulations of products can be considered as a worst case. The following exposure scenario, as proposed in CEC (1996), can be used for the PEC-estimation:

Quantity used at a single site: 55 t/a Release fraction to waste water: 0.5%

Duration of release: 300 d/a => daily release rate: 0.92 kg/d

A concentration at a distance of 100 m from the source of  $PEC_{local\_air} = 0.25 \mu g/m^3$  and an average deposition rate of  $DEP_{total} = 0.4 \cdot 10^{-9} \text{ kg.m}^{-2}.d^{-1}$  can be derived by the method described above.

#### 3.1.2.4 Use of o-cresol containing products

As the exact quantities consumed for the different applications are not known, no realistic exposure scenarios can be derived.

### 3.1.2.5 Monitoring data

The following air monitoring results are available, as described in the IUCLID Data set:

location	date	n	result	reference
Portland, USA, urban residential area	1984	n.a.	$0.051 - 0.13 \text{ g/m}^3$	Leuenberger et al.,
			_	1985
USA, close to source areas	1982	54	mean: 1.6 ppb	Brodzinski & Singh,
			maximum: 29 ppb	1982
Japan, near a phenolic resin factory	1978	1	40 ppb	Hoshika & Muto,
				1978

These results are in close agreement with the above estimated concentrations.

#### 3.1.3 Terrestrial compartment

The main route of exposure of the terrestrial compartment is by wet and dry atmospheric deposition. As the adsorption to sewage sludge in the STP is low, the release to soil due to sewage sludge application as fertiliser can be neglected. The highest deposition rate estimated above,  $DEP_{total} = 6.0 \cdot 10^{-9} \text{ kg.m}^{-2}.d^{-1}$ , will be used to estimate the resulting soil concentration, according to the method described in CEC (1996). The input parameters and intermediate calculation results are presented in the table below.

	Model calculations for soil concentration			
	Partitioning between soil and pore water			
D	Density of air	RHO_air	1,3	kg_air/m <sup>3</sup> _air
D	Density of water	RHO_water	1000	kg_water/m <sup>3</sup> _water
D	Density of the solids in soil	RHO_solid	2500	kg_solid/m <sup>3</sup> _solid
D	Volume fraction air in soil	Fair_soil	0,2	m <sup>3</sup> _air/m <sup>3</sup> _soil
D	Volume fraction water in soil	Fwater_soil	0,2	m <sup>3</sup> _water/m <sup>3</sup> _soil
D	Volume fraction solids in soil	Fsolids_soil	0,6	m <sup>3</sup> _solids/m <sup>3</sup> _soil
О	Bulk density of the (wet) soil	RHO_soil	1700	kg_wet soil/m <sup>3</sup> _soil
S	n-octanol/water partition coefficient	log Pow	2	-
D	Fraction organic carbon in soil	Foc_soil		kg_oc/kg_solid
	Fraction organic matter in soil	Fom_soil	0,034	kg_om/kg_solid
S	Organic carbon-water partition coefficient	Koc	0,022	m <sup>3</sup> _water/kg_oc
О	Organic matter-water partition coefficient	Kom	0,013	m <sup>3</sup> _water/kg_om
О	Solids-water partitioning coefficient in soil	Kp_soil	0,00044	m <sup>3</sup> _water/kg_solid
О	Total soil-water partitioning coefficient	Ksoil_water	0,86	m <sup>3</sup> _water/m <sup>3</sup> _wet soil
	Partitioning between water and air			
S	Henry's law coefficient	Henry	0,1	Pa.m <sup>3</sup> /mol
О	Air-water partirion coefficient	Kair_water	4,22E-5	-
	Characteristics of soil and soil use			
D	Amount of sludge applied onto agricultural soil	APPL_agri	0,5	kg_dry sludge/m <sup>2</sup>
D	Depth of agricultural soil	DEPTHagri	0,2	m
	Derivation of removal rate constants			
О	Pseudo first order rate constant for volatilisation	kvolat_agri	0,00039	$d^{-1}$
S	Pseudo first order rate constant for biodegradation	kbio_soil	0,0230	
О	Pseudo first order rate constant for leaching	kleach_agri	0,00279	d <sup>-1</sup>
О	First order rate constant for removal	k_agri	0,0262	d <sup>-1</sup>
	Concentration in soil through aerial deposition			
S	Annual average deposition flux	DEPtotal	6,00E-9	kg_chem/m <sup>2</sup> /d
О	Aerial deposition flux per kg of soil	Dair_agri	1,76E-11	kg_chem/kg_soil/d
О	Initial concentration after 10 a of aerial deposition	Cdep_agri10(0)		kg_chem/kg_soil
О	Local concentration in soil	PEClocal		kg_chem/kg_soil
Ο			= 0,67	μg/kg_soil
О	Total concentration in soil porewater	PEClocal	1,33E-06	kg_chem/m <sup>3</sup> _water
О			= 1,33	μg/l

D: default value according to CEC (1996)

# **Monitoring data**

O: calculated value based on other indicated parameters

S: value specific to the substance or site

No monitoring results for soil are available. For groundwater, concentrations from undefined sources are reported in the STORET data base (US-EPA, 1993). They range from 0.9 to100,000 g/l with a mean concentration of 234.3 g/l (1,848 samples).

These measured concentrations are much higher than the estimated concentrations in soil pore water. Many of the ground water contaminations could be due to leakages from storage tanks of petroleum products which naturally contain o-cresol. This route of exposure was not considered in the above estimations, as it is not directly linked to the production and use of o-cresol. The result from the monitoring of groundwater will nevertheless be used for the estimation of the concentration in drinkingwater (see below).

# 3.1.4 Non compartment specific exposure relevant to the food chain (secondary poisoning)

As a low BCF of 10.7 has been determined with o-cresol, its potential for biomagnification through the food chain is low and a risk assessment for secondary poisoning does not seem to be necessary.

#### 3.2 Effects assessment: Hazard identification and concentration - effect assessment

#### 3.2.1 Aquatic compartment

#### Available effect data

In the following, the most relevant results from acute toxicity tests with aquatic organisms are presented:

#### vertebrates:

The lowest acute effect concentration was determined with *Leuciscus idus* (48h-LC50 = 2 mg/l) in a ring-test for the elaboration of a DIN-method (Dietz & Traub, 1978). With an improved draft of the method, the same test yielded a 48h-LC50 of 10 mg/l (Wellens, 1982). The latter result will be retained.

The test results with other fish species shows that <u>salmonids</u> are the most sensitive to o-cresol:

Oncorhynchus mykiss	96h-LC50	8.4 mg/l
(flow-through, measured concentrations) (Degraev	e, 1980)	
Oncorhynchus mykiss	96h-LC50	7.0 mg/l
(no data on test conditions available) (Howland, 19	969)	
Salmo trutta	96h-LC50	6.2 mg/l
(no data on test conditions available) (Howland, 19	969)	
Salvelinus fontinalis	96h-LC50	7.2 mg/l
(no data on test conditions available) (Howland, 19	969)	

Unfortunately only the first result with *Oncorhynchus mykiss* could be validated, but the results from the other tests are consistent with the first one.

A further test with embryos of *Trutta iridea* i.e. Rainbow trout i.e. *Oncorhynchus mykiss* further confirmed this tendency: 24h-LC50 = 2.3 mg/l (Albersmayer & Erichsen, 1959), and showed the increased sensitivity of early life stages.

For most other fish species, the acute LC50-values were determined to range between 10 and 20 mg/l.

Test results with <u>amphibians</u> are also available:

Ambystoma mexicanum (Salamander)	48h-LC50	40 mg/l
(static, nominal concentrations) (Slooff, 1983)		
Xenopus laevis (clawed toad)	48h-LC50	38 mg/l
(static, nominal concentrations) (Slooff, 1983)		

#### invertebrates:

Tests have been performed with many different species. *Daphnia magna* and *Daphnia pulex* appeared to be the most sensitive. The lowest acute EC-50 value of 5 mg/l (Parkhurst, 1979) could not be validated due to the lack of details on the test conditions. The other results consistenly lie between 9.2 and 23.5 mg/l.

#### plants:

Algae seem to be consistently less sensitive to o-cresol than fish or crustaceans. Only NOEC-values are available, the lowest being:

Scenedesmus quadricauda	8d-NOEC	11 mg/l (Bringmann & Kühn, 1979)
Microcystis aeruginosa	8d-NOEC	6.8 mg/l (Bringmann & Kühn, 1976)

The results with submerged macrophytes (Nobel, 1983) cannot be considered to be valid, as only cut-off shoots were tested.

#### bacteria

the most relevant result is:

Pseudomonas putida	16h-NOEC	33 mg/l
(effect: growth inhibition) (Bringmann	n & Ktin, 1976)	

# Determination of PNECagua

Only acute effect data are available for fish and crustaceans. As a multitude of species were tested against the effects of o-cresol, an assessment factor of 100 would seem to be appropriate. Applied to the lowest 96h-LC50 with fish i.e. 6.2 mg/l: PNEC<sub>aqua</sub> = 6200/100 = 62 g/l

This PNEC-value seems to underestimate the chronic toxicity from phenols to fish. Indeed, (Q)SARs for phenols, based on toxicity tests with *Oncorhynchus mykiss* would predict the following acute and chronic effect concentrations (US-EPA, 1995b):

96h-LC50	14 mg/l
30d-NOEC (ELS)	1.8 mg/l
60d-NOEC (ELS)	0.12 mg/l

With daphnids, a chronic NOEC of 1.5 mg/l is estimated by (Q)SARs (US-EPA, 1995b). This is in agreement with the data reported by Klin et al. (1989) for p-cresol with *Daphnia magna*:

21d-NOEC	1.0 mg/l
----------	----------

It has indeed been shown (Devillers, 1988) that there were no significant differences in the magnitude of acute ecotoxicity to *Daphnia magna* of the 3 cresol isomers, with the *para* isomer only slightly more toxic than the *ortho* or *meta* isomers.

Using the above estimated chronic test results, an alternative PNEC can be determined, using an assessment factor of 10, considering that long-term test results are available for species out of three trophic levels:

$$PNEC_{aqua} = 120 / 10 = 12 \mu g/l$$

This lower PNEC of 12 g/l will be used in the risk characterisation.

# **Determination of PNEC**<sub>microorganisms</sub>

As effect data are available with specific aerobic bacterial populations (*Pseudomonas putida*), a safety factor of 10 applied to the lowest effect concentration seems to be sufficient.

Therefore:

$$PNEC_{microorganisms} = 33 / 10 = 3.3 \text{ mg/l.}$$

#### **Sediment**

Due to the low sediment/water partition coefficient, the assessment of the sediment is covered by the assessment for the water compartment, and no separate estimations for the sediment are necessary.

# 3.2.2 Terrestrial compartment

No test results with terrestrial organisms are available. Therefore, for an indicative risk assessment for the soil compartment, the aquatic PNEC will be used and compared to the concentration in soil pore water:

$$PNEC_{soil} = 12 \mu g/l$$
 (soil pore water)

#### 3.2.3 Atmosphere

No data on effects of o-cresol upon environmental organisms through the gas phase are available.

# 3.2.4 Non compartment specific exposure relevant to the food chain (secondary poisoning)

As a low BCF of 10.7 has been determined with o-cresol, its potential for biomagnification through the food chain is low and a risk assessment for secondary poisoning does not seem to be necessary.

#### 3.3 Risk characterisation

## 3.3.1 Aquatic compartment

The comparison between the estimated aquatic concentrations for the different life stages of o-cresol and the Predicted No Effect Concentration for the aquatic compartment is presented in the following table:

1.6	PEC [ug/l]	DEC/DNEC
life-stage	PEC [µg/I]	PEC/PNEC

production		
standard scenario	2.6	0.22
petroleum refining*	12.3	1.02
specific data from 1 producer	0.05	< 0.01
use as a chemical intermediate		
standard scenario	1.8	0.15
organics and plastics*	50.3	4.19
plastics and synthetics*	168.6 8.3	14.05 0.69
pharmaceuticals*	8.3 121.7	10.14
organic chemicals*	1211,	1011
formulation of o-cresol containing products		
standard scenario	16.5	1.37
paint and ink*	3.1	0.26
soaps and detergents*	4.4	0.37
synfuels*	29.0	2.42
use of o-cresol containing products in different		
industrial activities:		
timber products*	10.5	0.87
printing and publishing*	1.1	0.09
non-ferrous metals*	3.6	0.3
	7.2	0.6
textile mills*	6.0 43.5	0.5 3.6
pulp and paper*	43.3 46.1	3.8
rubber processing*	0.3	0.02
auto and other laundries*	0.2	0.02
gum and wood industry*	23.7	1.97
aluminum*	0.5	0.04
	0.4	0.04
electronics*		
electroplating*		
oil and gas extraction*		

<sup>\*</sup> based on measured concentrations in effluents

Using the monitoring data from the STORET data base, a PEC/PNEC-ratio of 0.91, using the mean value, and of 5.6, using the maximum value, can be derived.

Many of the above derived PEC/PNEC-values are > 1. A risk to the aquatic ecosystem has therefore to be assumed. Unfortunately, the PNEC is based on (Q)SAR estimations for the long-term effects upon fish. In a first step, this (Q)SAR-value should be verified by conducting a 60 day early life stage test with *Oncorhynchus mykiss*.

# 3.3.2 Atmosphere

No data on effects of o-cresol upon environmental organisms through the gas phase are available. Due to the low residence time of o-cresol in the atmosphere (half-life < 10 days), the ozone depletion potential and global warming potential is probably negligible.

#### 3.3.3 Terrestrial compartment

No test results with terestrial organisms are available. Only an indicative risk assessment with the estimated concentration in soil water can be performed, by comparison with the PNEC determined for the aquatic compartment. The highest estimated concentration is 1.33 g/l and:

#### PECsoil/PNECsoil = 1.33 / 12 = 0.11

As PEC/PNEC < 1, it can be assumed that o-cresol presents no risk to the terrestrial compartment, due to its production and use. No test with terrestrial organisms are necessary.

Much higher concentrations in soil might nevertheless occur, due to spills or leakages in storage tanks of petroleum products, which naturally contain o-cresol.

### 3.3.4 Non compartment specific exposure relevant to the food chain (secondary poisoning)

As a low BCF of 10.7 has been determined with o-cresol, its potential for biomagnification through the food chain is low and the risk for secondary poisoning is probably negligible.

#### 4. HUMAN HEALTH

## 4.1 Exposure assessment

#### 4.1.0 General discussion

Human exposure to cresols may occur in facilities which manufacture, process or use cresols. o-Cresol is mainly used as an intermediate in manufacturing of plastics, resins and pesticides. Nevertheless, the exposure through cresol-containing products is expected to be substantial.

According to the US-EPA (1986), approximately 126 000 - 300 000 individuals are exposed to cresols at the workplace in the USA. The largest sub-group is formed by mechanics (approx. 148000) exposed to cresol-containing cleaning compounds. This use involves using cresol-based cleaning products in a tank-dipping process used to clean large items, usually automobile carburettors. New techniques, essentially closed, have been developed which have minimized the exposure. These new products are estimated to have half of the market (US-EPA, 1986).

Cresols are not found in any end-use consumer products in the USA (US-EPA, 1986) and the product registers in Europe show that cresol-containing consumer products tend to disappear.

# 4.1.1 Occupational exposure

Two routes of occupational exposure to o-cresol should be considered: inhalational and dermal.

Some occupational exposure data on cresols (o, m, p) have been reported:

- -<0.44 mg/m<sup>3</sup> (0.1 ppm) in a pilot coal gasification plant in US (Dreibelbis & al, 1985).
- 0,6 mg/m<sup>3</sup> (0,14 ppm) in a <u>Finnish facility using creosote for</u> wood impregnation during periods in which the cylinder used for impregnation was opened (Heikkila & al., 1987).

It is stated by the Creosols Task Force (as cited in US-EPA, 1986) that TWA-8 hour exposures of as high as 1 ppm (4.4 mg/m³) are sustained only by a very few of the most highly exposed workers in cresols (o, m, p) manufacturing facilities.

Exposure from production or use as intermediate: inhalation route.

A level of 1 ppm (4.4 mg/m<sup>3</sup>) of o-cresol is used for calculating the estimated human exposure (EHE). It should be borne in mind that in most countries a 8h-TWA limit concentration at the workplace of 5 ppm (22 mg/m<sup>3</sup>) for the sum of cresol isomers is established.

The EHE level, expressed in terms of dose per unit weight (mg/kg) can be calculated as follows:

```
EHE - worker = C \times V \times t \times B_{ihl} / BW
```

with C = air concentration  $(mg/m^3)$ 

V = ventilation rate of an adult worker (15 l/mn or 0.9 m<sup>3</sup>/h) t = time period of exposure (8 h per working day)  $B_{ihl} =$  bioavailability for inhalation (assumed to be 0.75)

BW = body weight for an average adult worker (70 kg)

EHE - worker =  $4.4 \times 0.9 \times 8 \times 0.75 / 70 = 0.34 \text{ mg/kg bw/d}$ 

# exposure from a liquid preparation containing less than 1% o-cresol : dermal and inhalational exposure.

In the EU, preparations containing more than 1 % o-cresol have to be labelled as corrosive. So, prevention measures are expected to be taken. For concentrations of 1 % or less than 1 %, assessment of occupational exposure via dermal route may be determined according to the model EASE as presented in CEC (1996).

The EHE level, expressed in terms of dose per unit weight (mg/kg) is calculated as follows:

EHE- worker = 
$$C \times C_1 \times S / BW$$

For a liquid product e.g. cleaning agent or paint stripper which contains 1 % o-cresol, with a wide dispersive use, by direct handling, under incidental contact, the contact level is estimated as  $C_1 = 1$  mg/cm<sup>2</sup>/d. Up to 5 mg/cm<sup>2</sup>/d can be expected for intermittent exposure, which could be expected for open handling of cleaning agents.

```
EHE-worker = 0.01 \times 1 \times 2000 / 70 = 0.28 \text{ mg/kg/d} for incidential contact and EHE-worker = 0.01 \times 5 \times 2000 / 70 = 1.40 \text{ mg/kg/d} for intermittent contact
```

If we consider that the inhalation exposure is as high as in the precedent case, the total workplace exposure via both inhalation and dermal routes are assessed as:

EHE (inhalation) + EHE (dermal) = 
$$0.34 + 0.28 = 0.62$$
 mg/kg/d for incidential contact =  $0.34 + 1.40 = 1.74$  mg/kg/d for intermittant contact

#### 4.1.2 Consumer exposure

As o-cresol containing consumer products seem to disappear from the market, no exposure assessment needs to be performed for consumers.

#### 4.1.3 Indirect exposure via the environment

Based on the above estimated environmental concentrations, the human exposure via the environment can be estimated, with the method described in CEC (1996) (see Annex 1). For a preliminary assessment, the highest local environmental concentration have been used for a "worst case" estimation:

Total concentration in soil	PECsoil	0.67 μg/kg_wet soil
Dissolved concentration in surface water	PECaqua	167 μg/l
Total concentration in air	PECair	$4 \mu g/m^3$
Dissolved concentration in groundwater	Cgrw	234,3 μg/l
Concentration in porewater in soil	Cporew	$1,30 \mu g/l$

The resulting estimated human intake rates are:

Total daily intake for humans	DOSEtot	10	ug/kg bw/d
Daily dose through intake of air	DOSEair	0.000857	μg/kg bw/d
Daily dose through intake of milk	DOSEmilk	0.000889	μg/kg bw/d
Daily dose through intake of meat	DOSEmeat	0.000150	μg/kg bw/d
Daily dose through intake of belowground plants	DOSEroot	0.014714	μg/kg bw/d
Daily dose through intake of aboveground plants	DOSEstem	0.152464	μg/kg bw/d
Daily dose through intake of fish	DOSEfish	2.935621	μg/kg bw/d
Daily dose through intake of drinking water	DOSEdrw	6.694286	μg/kg bw/d

The highest intake rates are to be expected through drinking water and fish, the other routes being negligible.

# 4.1.4 Combined exposure

Compared to the occupational exposure, the indirect exposure via the environment is negligible and therefore the highest estimated occupational exposure of 1.74 mg/kg bw/d is retained for the risk characterisation.

# 4.2 Effects assessment: Hazard identification and dose - response assessment

#### 4.2.1 Toxico-kinetics, metabolism and distribution

o-Cresol is absorbed across the respiratory and gastrointestinal tracts and through the intact skin. The primary metabolic pathway is conjugation with glucuronic acid and inorganic sulfate. Minor pathways include hydroxylation of the benzene ring. At physiological pH, the conjugated metabolites are ionized to a greater proportion than the cresol itself, thus reducing renal reabsorption and aiding urinary excretion. Significant amounts of o-cresol are excreted in the bile, but most of it is reabsorbed from the intestine following hydrolysis by gut bacteria. The main route for removing cresols from the body is renal elimination. (IPCS, 1994)

# 4.2.2 Acute toxicity

By <u>oral route</u>, the LD50 for rats is 121 mg/kg by undiluted administration (Bio Fax, 1969) and 1470 mg/kg when administered at 10% in olive oil (Uzhdavini, 1974). For rabbits and mice, the LD50-values, when administered at 10% in olive oil, are 940 and 344 mg/kg respectively (Uzhdavini, 1974), suggesting a higher sensitivity in mice compared to rats and rabbits.

By <u>inhalation</u> of a vapour/aerosol mixture, a LC50 of 178 mg/m³ was found for mice (exposure duration not indicated) (Uzhdavini, 1972). For rats, a LC50 of 29 mg/m³ is reported (Pereima, 1975). Rabbits survived a concentration of 1220 mg/m³ over a duration of 1 hour (Bio Fax, 1969).

By <u>dermal</u> application, LD50 values of 620 mg/kg have been determined for rats (Uzhdavini, 1974) and 890 - 1380 mg/kg for rabbits (Vernot et al., 1977; Bio Fax, 1969).

### 4.2.3 Corrosiveness and irritation

o-Cresol proved to be corrosive to skin and highly irritating to eyes of rabbits (Vernot et al., 1977; Schreiber, 1980; Bio Fax, 1969; Kuroki et al., 1988; Younger Laboratories, 1974).

The threshold concentration for mucosal irritation in 8 humans out of 10 was determined to be 6 mg/m<sup>3</sup> (duration of exposure not specified) (Uzhdavini, 1972).

# 4.2.4 Repeated dose toxicity

Results of the most relevant repeated dose toxicity studies are summarized in the following table:

Study	NOAEL	LOAEL	Effects		Ref.
Inhalation toxicity (1)					
Subacute, mice (30 d, 2h/d, 6d/w, 50 mg/m <sup>3</sup> )	<50 mg/m <sup>3</sup>			no mortality but respiratory irritation, reduced weight gain and mummification of the tails of some animals; muscle and nerve cell dystrophy, hepatic and kidney proteolysis	Uzhdavini 1972
Semichronic, rat (16 wk, 4 - 6 h/d, 5 d/w, 9 mg/m <sup>3</sup> )	< 9 mg/m <sup>3</sup>			behavioural depression; elevated leucocyte counts in the males, depressed erythroid bone marrow elements, increased hexobarbital narcosis time and morphological changes in in respiratory tissues	Uzhdavini 1972
Semichronic, guinea pig (16 wk, 4 - 6 h/d, 5 d/w, 9 mg/m <sup>3</sup> )	9 mg/m <sup>3</sup>			decreased R-wave component in the electrocardiogram; unspecified changes in the hemoglobin concentration	Uzhdavini 1972
Oral toxicity					
Subacute, rat (4 wk, oral feed, males and females; 27, 87-89, 266-271, 861-881, 2610-2510 mg/kg bw/d)	266-271 mg/kg bw/d	861-881 mg/kg bw/d	all doses	no death, reduced feed consumption during the first week; no gross or microscopic lesions	NTP, 1992
			≥ 861/881	increased liver and kidney weight relative to brain weight	
Subacute, mouse (4 wk, oral feed, males and females; 66-82, 193-280, 558-763, 1650-	193-280 mg/kg bw/d	558-763 mg/kg bw/d	≥ 558/763	increased liver weight relative to brain weight	NTP, 1992
1670, 4480-5000 mg/kg bw/d)			≥ 1670	uterine atrophy	
			5000	ovarian atrophy	
Subacute, ferret (4 wk, oral feed, males and females; 45-80, 85-150, 140-240, 290-530,	85-150 mg/kg bw/d	140-240 mg/kg bw/d	≥ 140/240	increased liver and kidney weight relative to brain weight	Hornshaw et al. 1986
400-720 mg/kg bw/d)			290/530	increased testis weight	

55, 80-120, 125-190, 200-300, 320-480 mg/kg bw/d) ≥ 200/300 decrease in red blood cell count  Semichronic, rat (13 wk, oral feed, males and females, 126- mg/kg bw/d mg/kg bw/d mg/kg bw/d liver weight; ≥ 510/513 bone marrow hypocellularity;	et al. 1986 NTP, 1992
320-480 mg/kg bw/d) $\geq 200/300$ decrease in red blood cell countSemichronic, rat (13 wk, oral feed, males and females, 126-129, 247-256, 510-513, 1017-1019)247-256 bw/d mg/kg bw/d mg/kg bw/d mg/kg bw/d bw/d bw/d liver weight;	NTP, 1992
Semichronic, rat (13 wk, oral feed, males and females, 126-129, 247-256, 510-513, 1017-129, 247-256, 24	NTP, 1992
feed, males and females, 126- 129, 247-256, 510-513, 1017-   mg/kg bw/d   mg/kg bw/d   liver weight; ≥ 510/513   bone marrow hypocellularity;	NTP, 1992
129, 247-256, 510-513, 1017- ≥ 510/513 bone marrow hypocellularity;	
1001 0004 0000 // 1 //	
1021, 2024-2028 mg/kg bw/d) ≥ 1017/ reduced body weight gain	
1021 significant dose related increase in	
total bile acids in males and	
all doses females;	
no adverse effects on sperm motility	
or concentration; estrus cycle in	
females seemed to be lengthened	
	TRL, 1986
gavage, males and females; bw/d bw/d on day 1 of the study during the	
50, 175, 450, 600 mg/kg hour following gavage	
bw/d; administration, and one of these	
neurotoxicity study animals became comatose during that time	
that time ≥ 450	
mortality, significant neurological	
events	
	NTP, 1992
oral feed, males and females, mg/kg bw/d mg/kg bw/d liver weight;	1,11,1772
199-237, 400-469, 790-935, 790/935 reduced body weight	
1460-1663, 2723-3205 mg/kg	
bw/d)	

Notes: (1) only limited data on test conditions are available for these studies

#### Conclusion:

Subchronic inhalational exposure (4 months) of rats to o-cresol causes reduced locomotor activity, inflammation of respiratory tissues and changes in the liver. No NOAEL could be determined for this route. Oral exposure of up to 13 weeks of mice and rats resulted in mortality, tremors, reduced body weights, hematologic effects and increase in organ weights. An overall subchronic NOAEL of 50 mg/kg bw/day can be derived.

#### 4.2.5 Mutagenicity

*In vitro* DNA repair assays (unscheduled DNA synthesis) were negative in rat hepatocytes (Litton Bionetics, 1981a). o-Cresol was not mutagenic to *Salmonella typhimurium* nor to mouse lymphoma cells (Litton Bionetics, 1981b). In *Drosophilia melanogaster*, sex-linked recessive lethal mutations were not induced (Hazleton, 1989a).

Chromosomal aberrations were induced in CHO cells in both the presence and absence of S9 mix (Hazleton, 1988). In mice *in vivo*, there was no induction of micronuclei in peripheral blood erythrocytes (NTP, 1992).

Sister-chromatid exchanges (SCE) were induced in CHO cells (Litton Bionetics, 1981c). In cultured human fibroplasts, the response was weak even at the highest non-toxic concentration tested (8 mM) (Cheng & Kligermann, 1984). o-Cresol did not increase SCE in mouse bone marrow, lung or liver cells in *in vivo* studies (Cheng & Kligermann, 1984).

No dominant lethal effects were observed following treatment of male mice (Hazleton, 1989b).

Antimutagenic effects of o-cresol have been demonstrated after administration of methylnitrosoguanidine (MNNG) - induced mutagenesis in *Escherichia coli* (Kushi & Yoshida, 1987).

In summary, these data indicate that o-cresol can induce chromosomal aberrations and increase SCEs *in vitro* but does not do so *in vivo*.

### 4.2.6 Carcinogenicity

There are no adequate bioassays or chronic studies available to assess the carcinogenic potential of ocresol.

The tumor-promoting ability of o-cresol using the mouse skin-painting model was investigated (Boutwell & Bosch, 1959). Both the average number of skin papillomas per mouse and the percentage of exposed mice with at least one papilloma were increased by treatment with o-cresol. No carcinomas were observed. It should be noted that the vehicle used was benzene, a known carcinogen. The presence of benzene did not appear to affect the results, however, since no papillomas were observed in benzene-treated controls. This study suggests cresols may act as promoters.

## 4.2.7 Toxicity for reproduction / developmental toxicity / teratogenicity

In the subchronic repeated dose toxicity study with mice and rats (NTP, 1992), no adverse effects on sperm motility or concentration were observed up to a dose of 2723/3205 or 2028/2024 mg/kg bw/day respectively. An increased length in the oestrous cycle was observed in mice at 2723/3205 mg/kg bw/day. Increased testis weight was observed though in ferrets dosed 290/530 mg/kg bw/day (Hornshaw et al., 1986).

A developmental study in rats (gd 6 - 15) showed slight fetotoxicity in the highest dose group (450 mg/kg bw/day) only. The NOEL for maternal and developmental toxicity was 175 mg/kg bw/day (Union Carbide, 1988a). In rabbits, o-cresol caused fetotoxicity in the highest dose group of 100 mg/kg bw/day. The NOEL for developmental toxicity was established at 50 mg/kg bw/day (Union Carbide, 1988b).

Reproduction studies were performed with mink (one generation; Hornshaw et al., 1986), rats (two generations; Union Carbide, 1989) and mice (two generations; Izard et al., 1992). None of these studies indicated increased risks to offspring from o-cresol in the absence of parental effects. NOAELs for parental toxicity were 25-40 mg/kg bw/day for mink and 30 mg/kg bw/day for rats.

#### 4.3 Risk characterisation

o-Cresol is not flammable. Cresols emit highly toxic vapors when heated to decomposition. o-Cresol is corrosive to skin and irritant to eyes.

The overall subschronic NOAEL based on the available test data with mammals as described above can be fixed at 30 mg/kg bw/d.

#### Consumer

As o-cresol containing consumer products seem to have disappeared from the market, no exposure assessment needs to be performed for consumers.

#### Workers

Exposure from production or use as intermediate: inhalation route:

The estimated human exposure dose during the production of o-cresol or its use as an intermediate, is 0.34 mg/kg bw/d. The ratio NOAEL/EHE is:

$$NOAEL/EHE = 30/0.34 = ca. 90$$

Considering the limit concentration of 22 mg/m<sup>3</sup> (sum of cresol isomers) valid in many OECD-countries, and corresponding to a daily dose of 1.7 mg/kg bw/day, the margin of safety would be ca. 18.

Exposure from a liquid preparation containing less than 1% o-cresol:

The estimated human exposure dose for the use of o-cresol containing products is 0.62 - 1.74 mg/kg bw/d. The ratio NOAEL/EHE is:

NOAEL/EHE = 
$$30/0.62$$
 = ca. 48  
resp.  $30/1.74$  = ca. 17

The above 'margins of safety' appear to be rather low and there might be a risk to workers. This is further confirmed by the 4 month inhalational NOAEL of  $< 9 \text{ mg/m}^3$  when compared to the estimated exposure concentration of 4.4 mg/m<sup>3</sup>.

### Indirect exposure via the environment

The estimated human exposure dose through the environment is 0.01 mg/kg bw/d. The ratio NOAEL/EHE is:

$$NOAEL/EHE = 30/0.01 = ca. 3000$$

This margin of safety seems to be sufficiently high. No risk is to be expected to humans through the exposure of o-cresol via the environment.

## 5 CONCLUSIONS AND RECOMMENDATIONS

A risk to the aquatic ecosystem has to be assumed. Unfortunately, the PNEC is based on (Q)SAR estimations for the long-term effects upon fish. In a first step, this (Q)SAR-value should be verified by conducting a 60 day early life stage test with *Oncorhynchus mykiss*.

As far as human health is concerned, the estimated 'margins of safety' for workers are very low and a risk for workers has to be assumed. Furthermore, no comprehensive data on chronic toxicity and carcinogenicity are available.

Studies on chronic toxicity and carcinogenicty should be conducted and the inhalation route should be preferred, due to the effects observed in the 120 d inhalation route studies.

In the mean time, in case the 'margins of safety' cannot be raised by better exposure estimates at the workplace, protective measures should be taken:

• a reduction of the limit concentration at the workplace (8-h time weighted average,TWA), at present 5 ppm (22 mg/m<sup>3</sup>), should be considered;

• the threshold specific concentration of o-cresol in preparations requiring warning labelling should be reduced (classification and labelling according to EU legislation);

 because of the increasing tendency for substitution, the use of o-cresol in consumer products should be rviewed.

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**Annex I**: Model calculation for indirect exposure via the environment Input parameters and intermediate estimation results according to CEC (1996)

	T	1	
Total concentration in soil	PECsoil		mg/kg_wet soil
Dissolved concentration in surface water	PECaqua	0,167	=
Total concentration in air	PEC air		mg/m <sup>3</sup>
Dissolved concentration in groundwater	Cgrw	0,2343	
Concentration in porewater in soil (agric)	C_agric_porew	1,30E-03	-
Octanol-water partitioning coefficient	log Pow	2	
Vapour pressure	VP		Pa
Molecular weight	MOLW	0,10814	
Water solubility	SOL	26000	
Henry's law constant	Н	,	Pa.m <sup>3</sup> /mol
Aerobic biodegradation in surface water	DT50	15	d
Partitioning between soil and pore water			
Density of air	RHO_air		kg_air/m³_air
Density of water	RHO_water		kg_water/m³_water
Density of the solids in soil	RHO_solid	2500	kg_solid/m³_solid
Volume fraction air in soil	Fair_soil	0,2	m³_air/m³_soil
Volume fraction water in soil	Fwater_soil	•	m <sup>3</sup> _water/m <sup>3</sup> _soil
Volume fraction solids in soil	Fsolids_soil	0,6	m³_solids/m³_soil
bulk density of the soil	RHO_soil	1700	kg_wet soil/m³_soil
Fraction organic carbon in soil	Foc_soil	0,02	kg_oc/kg_solid
Organic carbon-water partition coefficient	Koc	22	l/kg
		0,022	m³_water/kg_oc
solids-water partitioning coefficient in soil	Kp_soil	0,00044	m <sup>3</sup> _water/kg_solid
total soil-water partitioning coefficient	Ksoil_water	0,86	m <sup>3</sup> _water/m <sup>3</sup> _wet soil
Bioconcentration factors			
fish			
Volume fraction fat of fish	Ffat_fish	0,05	m <sup>3</sup> _fat/m <sup>3</sup> _wet fish
Bulk density of aquatic biota	RHO_bio	1000	kg_wet biota/m³_wet biota
Bioconcentration factor for fish	BCF	10,7	l_chem/kg_wet fish
concentration in fish	Cfish	1,7869	mg_chem/kg_wet fish
soil-plant			
Transportation stream concentration factor	TSCFcalc.	0,76860175	-
	1. checking	0,903	-
	2.checking	0,832	
value TSCF calculated (log Pow < -0.5 or log Pow>4.5)	-	0,76860175	-
Stem concentration factor	SCF	*	m <sup>3</sup> _xylem/kg_wet stem
Bioconcentration factor for stems	BCFstem_plant		(kg_chem/kg_wet stem)/(kg_chem/kg_wet soil)
Bioconcentration factor for roots	BCFroot_plant	3,691399983	(kg_chem/kg_wet soil) (kg_chem/kg_wet soil)
plant - water			/ \ <u>C</u> _ = 1
Partitioning between plant tissue and water	Kplant_water	1,444328235	m³_plant tissue/m³_water
volume fraction water in plant tissue	Fwater_plant	0,65	m <sup>3</sup> _water/m <sup>3</sup> _plant tissue
volume fraction lipids in plant tissue	Flipid_plant	0,01	m <sup>3</sup> _lipid/m <sup>3</sup> _plant tissue
correction (differences plant lipids and octanol)	b	0,95	
air-plant		1	
partition coefficient between leaves and air	Kleaf_air	1555,900595	m <sup>3</sup> _leaves/m <sup>3</sup> _air
Aerosol-plant partition coefficient	Kaerosol_plant		m <sup>3</sup> _air/kg_wet plant
Air-water partition coefficient	Kair_water	0,00092847	• .
Volumefraction air in plant	Fair_plant	0,3	
· · · · · · · · · · · · · · · · · · ·		0,5	

Volumefraction water in plant	Fwater_plant	0,4	-
Volumefraction lipids in plant	Flipid_plant	0,01	
Bulk density of plants	RHOplant	,	kg_wet plant/m³_plant
Gas-plant partition coefficient	Kriopiant  Kgas_plant		m <sup>3</sup> _air/kg_wet plant
CONjunge*SURFaer	Kgas_piant	0,0001	• .
Fraction of chemical associated with aerosol	Eags age	4,16665E-06	
	Fass_aer	4,10005E-00	-
[if known, the following constant may be added]			
pseudo-first order rate constant for elimination	kelim_plant	0	day <sup>-1</sup>
rate constant for metabolism in plants	kmetab_plant		day <sup>-1</sup>
rate constant for photolysis in plants	kphoto_plant		day <sup>-1</sup>
sink term	α	138,8613496	
leaf surface area	AREA_plant		m <sup>2</sup>
conductance (0,001m.s-1)	g_plant	· ·	m.d <sup>-1</sup>
shoot volume	Vleaf	0,002	
pseudo-first order rate constant for dilution by growth	kgrwth_plant	0,035	
source term grass	β	864,4959912	_
source term plant	β	864,4959912	mg/m³.d
transpiration stream (11.d-1)	Qtransp	1,00E-03	m <sup>3</sup> /d
Bioconcentration factor for plants through air	BCFair_plant	2,168251355	(kg_chem/kg_wet stem)/(kg_chem/m³_air)
Concentration in leafs (steady state) grass	Cleaf.grass	0,008893722	mg/kg_wet grass
Concentration in leafs (steady state)plant	Cleaf.plant	0,008893722	mg/kg_wet plant
Concentration in belowground plant parts	Croot	0,002682324	mg/kg
biotransfer to meat and milk			
Biotransfer factor for meat	BTFmeat.calc.	2,51189E-06	(mg_chem/kg_wet meat)/(mg_chem/d)
	1. checking	7,94E-07	(mg_chem/kg_wet meat)/(mg_chem/d)
	2. checking	7,94E-02	(mg_chem/kg_wet meat)/(mg_chem/d)
value BTFmeat calculated (log Pow < 1.5 or log Pow>6.5)	BTFmeat	2,51189E-06	(mg_chem/kg_wet meat)/(mg_chem/d)
Biotransfer factor for milk	BTFmilk.cal.	7,94328E-07	(mg_chem/kg_wet milk)/(mg_chem/d)
	1. checking		(mg_chem/kg_wet milk)/(mg_chem/d)
	2. checking		(mg_chem/kg_wet milk)/(mg_chem/d)
value BTFmeat calculated (log Pow <3 or log Pow>6.5)		·	(mg_chem/kg_wet milk)/(mg_chem/d)
Conversion from dry to total plant	CONVplant		kg_wet plant/kg_dry plant
Conversion from dry to total soil	CONVsoil		kg_wet soil/kg_solid
Daily intake of grass	IC_grass	16,9	kg_dry grass/d
Daily intake of soil	IC_soil	0,41	kg_dry soil/d
Daily intake of air	IC_air	122	m³/d
Daily Intake of drinking water	IC_drw	55	1/d
Concentration in meat	Cmeat	3,51062E-05	mg_chem/kg_wet meat
Concentration in milk	Cmilk	0,000111012	mg_chem/kg_milk
Purification of drinking water			
Purification factor system 1	Fsys1_pur	1	
Purification factor system 2	Fsys2_pur	1	
Worst case purification factor	Fpur	1	
Concentration in drinking water	C_drw	0,2343	mg_chem/l
Total daily intake for humans			
Daily intake of drinking water	IHdrw	2	1.d <sup>-1</sup>
Daily intake of fish	IHfish	0,115	kg/d
Daily intake of aboveground plants	IHstem		kg/d

Daily intake of belowground plants	IHroots	0,384	kg/d
Daily intake of meat	IHmeat	0,301	kg/d
Daiy intake of milk	IHmilk	0,561	kg/d
Daiy intake of air	IHair	20	m³/d
Bioavailability through inhalational intake	BIOinh	0,75	-
Bioavailability through oral intake	BIOoral	1	-
Bodyweight of the human considered	BW	70	kg
Daily dose through intake of drinking water	DOSEdrw	0,006694286	mg_chem/kg_bw/d
Daily dose through intake of fish	DOSEfish	0,002935621	mg_chem/kg_bw/d
Daily dose through intake of aboveground plants	DOSEstem	0,000152464	mg_chem/kg_bw/d
Daily dose through intake of belowground plants	DOSEroot	1,47145E-05	mg_chem/kg_bw/d
Daily dose through intake of meat	DOSEmeat	1,50957E-07	mg_chem/kg_bw/d
Daily dose through intake of milk	DOSEmilk	8,89679E-07	mg_chem/kg_bw/d
Daily dose through intake of air	DOSEair	0,000857143	mg_chem/kg_bw/d
Total daily intake for humans	DOSEtot	0,01065527	mg_chem/kg_bw/d

EXTRACT FROM IRPTC DATA BASE

#### File: 17.01 LEGAL rn : 100140

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

rtecs no cas no :95-48-7 :GO6300000

: REG : ARG area type

\_\_\_\_\_ |subject|specification|descriptor| |-----AIR OCC MPC 

8H-TWA: 22MG/M3 (5PPM). SKIN ABSORPTION. (APPLIES TO ALL ISOMERS). entry date: OCT 1991 effective date: 29MAY1991

title: LIMIT VALUES FOR CHEMICAL SUBSTANCES IN THE WORKING ENVIRONMENT-RESOLUTION NO. 444/1991 OF THE MINISTRY OF WORK AND SOCIAL SECURITY (AMENDING REGULATION DECREE NO. 351/1979 UNDER LAW NO. 19587/1972: HYGIENE AND SAFETY AT WORK)

original : ARGOB\*, BOLETIN OFICIAL DE LA REPUBLICA ARGENTINA(ARGENTIAN OFFICIAL BULLETIN), 24170 , I , 1 , 1979

amendment: ARGOB\*, BOLETIN OFICIAL DE LA REPUBLICA ARGENTINA (ARGENTIAN OFFICIAL BULLETIN), 27145 , I , 4 , 1991

\*\*\*\*\*

#### File: 17.01 LEGAL rn: 302302

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 area : CAN rtecs no :G06300000 type : REG

subject|specification|descriptor| -----SALE | CONSM | PRO IMPRT | RQR GOODS LABEL \_\_\_\_\_

It is prohibited to sell, advertise, or import into Canada a product packaged as a consumer product that contains a corrosive chemical, including o-cresol, unless detailed labelling requirements are met. This prohibition is prescribed by Schedule I of the Hazardous Products Act(HPA), administered by the Department of Consumer and Corporate Affairs. It authorizes the prohibition and regulation of the sale, advertisement and importation of products that are or are likely to be a danger to the health or safety of the public. Products that fall under the purview of the Pest Control Products Act, the Food and Drugs Act, the Explosives Act or the Atomic Energy Control Act are, for the most part, exempt from the HPA.

entry date: MAY 1991 effective date: 01NOV1988

amendment: CAGAAK, CANADA GAZETTE PART II, 122 , 24 , 4625 , 1988

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#### File: 17.01 LEGAL rn: 302735

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

rtecs no :G06300000 :95-48-7 cas no

: CAN area type : REG \_\_\_\_\_\_ subject | specification | descriptor | -----USE OCC RQR STORE LABEL \_\_\_\_\_

Ingredient Disclosure List - Concentration: 1% weight/weight. The Workplace Hazardous Materials Information System (WHMIS) is a national system providing information on hazardous materials used in the workplace. WHMIS is implemented by the Hazardous Products Act and the Controlled Products Regulations (administered by the Department of Consumer and Corporate Affairs). The regulations impose standards on employers for the use, storage and handling of controlled products. The regulations also address labelling and identification, employee instruction and training, as well as the upkeep of a Materials Safety Data Sheet (MSDS). The presence in a controlled product of an ingredient in a concentration equal to or greater than specified in the Ingredient Disclosure List must be disclosed in the Safety Data Sheet.

effective date: 31DEC1987 entry date: APR 1991

amendment: CAGAAK, CANADA GAZETTE PART II, 122 , 2 , 551 , 1988

\*\*\*\*\*

#### File: 17.01 LEGAL rn: 400001

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :0-cresol

rtecs no :GO6300000 type : REG cas no :95-48-7 area : CZE

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|subject|specification|descriptor|
|----+----
AIR OCC MAC
_____
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TWA: 20.0MG/M3; CLV: 40.0MG/M3 (APPLIES TO ALL CRESOL ISOMERS) entry date: DEC 1991 effective date: MCH1985

title: DIRECTIVE NO. 46/1978 ON HYGIENIC REQUIREMENTS ON OCCUPATIONAL

ENVIRONMENT original : HPMZC\*, HYGIENICKE PREDPISY MINISTERSTVA ZDRAVOTNICTVI

CSR (HYGIENIC REGULATIONS OF MINISTRY OF HEALTH OF CSR), 39, , , 1978

amendment: HPMZC\*, HYGIENICKE PREDPISY MINISTERSTVA ZDRAVOTNICTVI CSR (HYGIENIC REGULATIONS OF MINISTRY OF HEALTH OF CSR), 58 ,

, , 1985

\*\*\*\*\*

#### File: 17.01 LEGAL rn: 400211

systematic name: Phenol, 2-methyl-

common name :O-cresol reported name :o-cresol

cas no :95-48-7

rtecs no :G06300000 type : REG : CZE

subject|specification|descriptor| -----AIR | AMBI | CLASS |

THE SUBSTANCE IS CLASSIFIED IN THE FOURTH GROUP OF AIR POLLUTANTS (ORGANIC GASES AND VAPOURS) (APPLIES TO ALL CRESOL ISOMERS)

entry date: DEC 1994 effective date: 1SEP1992

title: PROVISION OF FEDERAL COMMITTEE FOR ENVIRONMENT TO ACT NO. 309 FROM 9 JULY 1991 ON AIR PROTECTION AGAINST AIR POLLUTANTS original : SZCFR\*, SBIRKA ZAKONU CESKE A SLOVENSKE FEDERATIVNI REPUBLIKY (COLLECTION OF THE LAW OF CZECH AND SLOVAK FEDERAL REPUBLIC), , 84 , 2061 , 1991 amendment: SZCFR\*, SBIRKA ZAKONU CESKE A SLOVENSKE FEDERATIVNI REPUBLIKY (COLLECTION OF THE LAW OF CZECH AND SLOVAK FEDERAL REPUBLIC).

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File: 17.01 LEGAL rn: 400444

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

, 84 , 2404 , 1992

cas no :95-48-7 area : CZE rtecs no :GO6300000 type : REG

area : CZE

-----|subject|specification|descriptor| WASTE | INDST | CLASS RQR

THE SUBSTANCE IS CLASSIFIED AS HAZARDOUS WASTE COMPONENT. IT IS OR CAN BE DANGEROUS TO HUMAN HEALTH OR ENVIRONMENT. QUANTITY, SPECIFICATION, USE OR DISPOSAL OF THE WASTE MUST BE REPORTED TO AUTHORITIES. TRANSPORT AND DISPOSAL OF THE WASTE MUST BE PERFORMED IN ACCORDANCE WITH SPECIAL DIRECTIVE (APPLIES TO ALL CRESOL ISOMERS)

entry date: JAN 1992 effective date: 1AUG1991

title: PROVISION OF FEDERAL COMMITTEE FOR ENVIRONMENT WHICH DECLARES WASTE CLASSIFICATION AND CATALOGUE

original : SZCFR\*, SBIRKA ZAKONU CESKE A SLOVENSKE FEDERATIVNI REPUBLIKY (COLLECTION OF THE LAW OF CZECH AND SLOVAK FEDERAL REPUBLIC), , 69 , 1650 , 1991

\*\*\*\*\*

File: 17.01 LEGAL rn: 402326

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

rtecs no :GO63 cas no :95-48-7 area : CZE :GO6300000

|subject|specification|descriptor| -----AIR EMI MXL -----

GENERAL EMISSION LIMIT: 20 MG/M3 (IT APPLIES TO THE SUM OF ACETALDEHYDE, ANILINE, BENZYLCHLORIDE, DIETHYLAMINE, 1,2-DICHLOROETHANE, DICHLOROETHYLENE, DIMETHYLAMINE, ETHANOLAMINE, ETHYLACRYLATE, PHENOL, FORMALDEHYDE, CRESOLS, ACRYLIC ACID, FORMIC ACID, MERCAPTANES, METHYLACRYLATE, METHYLAMINE, NITROBENZENE, NITROPHENOLS, NITROCRESOLS, NITROTOLUENES, PYRIDINE, CARBONDISULFIDE, TETRACHLOROETHANE, TETRACHLOROETHYLENE, TETRACHLOROMETHANE, THIOETHERS, TOLUIDINES, TRICHLOROMETHANE AND TRICHLOROETHYLENE IF THEIR MASS FLOW > 100 G/H).

entry date: DEC 1994 effective date: 1SEP1992

title: PROVISION OF FEDERAL COMMITTEE FOR ENVIRONMENT TO ACT NO. 309 FROM 9 JULY 1991 ON AIR PROTECTION AGAINST AIR POLLUTANTS original : SZCFR\*, SBIRKA ZAKONU CESKE A SLOVENSKE FEDERATIVNI REPUBLIKY (COLLECTION OF THE LAW OF CZECH AND SLOVAK FEDERAL REPUBLIC), , 84 , 2061 , 1991 amendment: SZCFR\*, SBIRKA ZAKONU CESKE A SLOVENSKE FEDERATIVNI REPUBLIKY (COLLECTION OF THE LAW OF CZECH AND SLOVAK FEDERAL REPUBLIC), , 84 , 2398 , 1992

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#### File: 17.01 LEGAL rn: 502470

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

cas no :95-48-7 area : DEU rtecs no :GO6300000 type : REG

area : DEU \_\_\_\_\_

|subject|specification|descriptor| ----+----AIR EMI MPC

CRESOLS BELONG TO CLASS I. THE AIR EMISSIONS OF ORGANIC COMPOUNDS MUST NOT EXCEED (AS THE SUM OF ALL COMPOUNDS IN ONE CLASS) THE FOLLOWING MASS CONCENTRATIONS: CLASS I - 20 MG/M3 AT A MASS FLOW OF >= 0.1 KG/H; CLASS II - 100 MG/M3 AT A MASS FLOW OF >= 2 KG/H; CLASS III - 150 MG/M3 AT A MASS FLOW OF >= 3 KG/H. IF COMPOUNDS FROM DIFFERENT CLASSES ARE PRESENT, THE MASS CONCENTRATION MUST NOT EXCEED 150 MG/M3 AT A TOTAL MASS FLOW OF >= 3 KG/H.

entry date: JAN 1995 effective date: 01MCH1986

title: Technical Instructions on Air Quality Control (Technische Anleitung zur Reinhaltung der Luft)

original: GMSMA6, Gemeinsames Ministerialblatt, , 7 , 93 , 1986

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#### File: 17.01 LEGAL rn: 503205

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

rtecs no :GU6: cas no :95-48-7 area : DEU :GO6300000

\_\_\_\_\_

|subject|specification|descriptor| -----AIR OCC MAK -----

8H-TWA: 5 ML/M3 (PPM); 22 MG/M3 (20C, 101.3 KPA). LOCAL IRRITANT.

5MIN-STEL: 10 ML/M3 (PPM); 44 MG/M3; CEILING VALUE; 8X/SHIFT. DANGER OF CUTANEOUS ABSORPTION. APPLIES TO ALL ISOMERS OF CRESOL.

entry date: FEB 1996 effective date: 01JUL1995

title: Maximum Concentrations at the Workplace and Biological Tolerance Values for Working Materials (Maximale Arbeitsplatzkonzentrationen und Biologische Arbeitsstofftoleranzwerte)

original: MPGFDF, Mitteilung der Senatskommission zur Pruefung gesundheitsschaedlicher Arbeitsstoffe, 31 , , , 1995

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#### File: 17.01 LEGAL rn: 600182

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :2-Cresol

cas no :95-48-7 area : GBR rtecs no :GO63 type : REC :GO6300000

\_\_\_\_\_ |subject|specification|descriptor| -----AQ | METHD | RQR | DRINK |

Determines this substance in rivers, waters, sewage effluents and industrial effluents using the trimethyl-silylethers and gas chromatrography.

entry date: MCH 1995 effective date: 1981

title: Phenols in Waters and Effuents by Gas Liquid Chromatography or 3-Methyl-2-benzothiazoline Hydrazone.

original : SCAA\*\*, METHODS FOR THE EXAMINATION OF WATERS AND ASSOCIATED MATERIALS. THE STANDING COMMITTEE OF ANALYSTS (SCA), , , ,

\*\*\*\*\*

#### File: 17.01 LEGAL rn : 600519

systematic name: Phenol, 2-methyl-

common name :O-cresol reported name :2-Cresol

cas no :95-48-7 area : GBR rtecs no :GO6300000 type : REC

\_\_\_\_\_

subject|specification|descriptor| -----AQ | METHD | RQR | MONIT | DRINK |

Describes methods for determination of this substance in rivers and potable waters by electron capture gas chromatography of the pentafluorobenzoyl esters.

entry date: MCH 1995 effective date: 1988

title: The Determination of Microgram and Submicrogram Amounts of Individual Phenols in Rivers and Potable Waters.

original : SCAA\*\*, METHODS FOR THE EXAMINATION OF WATERS AND ASSOCIATED MATERIALS. THE STANDING COMMITTEE OF ANALYSTS (SCA), , , , 1988

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#### File: 17.01 LEGAL rn: 700548

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

rtecs no :GO6300000 type : REG cas no :95-48-7 area : IND cas no

\_\_\_\_\_

|subject|specification|descriptor| ----+-----

MANUF	RQ	)R
SAFTY	RQ	)R
STORE	RQ	)R
IMPRT	RQ	P.R

These rules define the responsabilities of occupiers of any industrial activity in which this toxic and hazardous substance may be involved. These responsabilities encompass: (a) assessment of major hazards (causes, occurrence, frequency); (b) measures to prevent accidents and limit eventual impairment to human health and pollution of the environment; (c) provision of relevant factual knowledge and skills to workers in order to ensure health and environmental safety when handling equipments and the foregoing chemical; (d) notification of the competent authorities in case of major accidents; (e) notification of sites to the competent authorities 3 months before commencing; (f)preparation of an on-site emergency plan as to how major accidents should be coped with; (q) provision of competent authorities with information and means to respond quickly and efficiently to any offsite emergency; (h) provision of information to persons outside the site, liable to be affected by a major accident; (i) labelling of containers as to clearly identify contents, manufacturers, physical, chemical and toxicological data; (j)preparation of a safety data sheet including any significant information regarding hazard of this substance and submission of safety reports to the competent authorities; (k) for the import of a hazardous chemical to India, importers must supply the competent authorities with specified information regarding the shipment. (applies to cresols) entry date: SEP 1992 effective date: 27NOV1989

title: THE MANUFACTURE, STORAGE AND IMPORT OF HAZARDOUS CHEMICALS RULES. 1989

original : GAZIN\*, THE GAZETTE OF INDIA, 787 , , , 1989

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### File: 17.01 LEGAL rn: 805313

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 area : JPN rtecs no :G06300000 type : REG

-----|subject|specification|descriptor| ------| CLASS | CLASS | RQR | RSTR

CRESOLS AND PREPARATIONS CONTAINING CRESOLS (>5%) ARE DESIGNATED AS DELETERIOUS SUBSTANCES.

entry date: JUN 1993 effective date: 00JAN1965

title: POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW amendment: JPPDL\*, POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW, ,

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### File: 17.01 LEGAL rn: 1024012

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 area : MEX rtecs no :GO6300000 type : REG

\_\_\_\_\_ subject | specification | descriptor | ------AQ AMBI MPC \_\_\_\_\_

1.5MG/L OF CRESOLS IN ESTUARIES

entry date: OCT 1982 effective date: 27JUN1973

title: DIARIO OFICIAL

original: DOMEX\*, DIARIO OFICIAL, 29 MCH , , 1167 , 1973

\*\*\*\*\*

File: 17.01 LEGAL rn: 1105322

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

cas no :95-48-7 rtecs no :GO6300000 area : RUS type : REG

|subject|specification|descriptor| |------| AIR AMBI PSL \_\_\_\_\_

0.028MG/M3 1X/D

entry date: SEP 1985 effective date: DEC1983

amendment: OBUAV\*, ORIENTIROVOCHNYE BEZOPASNYE UROVNI VOZDEISTVIA (OBUV) ZAGRAZNIAIUSHCHIKH VESHCHESTU V ATMOSFERNOM VOZDUKHE NASEKENNYKH MEST (TENTATIVE SAFE EXPOSURE LIMITS (TSEL) OF CONTAMINANTS IN AMBIENTAIR OF RESIDENTIAL AREAS), 2947-83 , , , 1983

\*\*\*\*\*

File: 17.01 LEGAL rn: 1105435

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

cas no :95-48-7 rtecs no :G06300000 area :RUS type :REG

|subject|specification|descriptor| ----+-----AQ | SURF | MAC \_\_\_\_\_

-----

SURFACE WATER FOR FISHING: 3UG/L

entry date: JUN 1982

amendment: PDKTV\*, PREDELNO-DOPUSTIMYE KONTSENTRATSII I ORIENTIROVOCHNYE BEZOPASNYEUROVNI VOZDEISTVIA VREDNYKH VESHCHESTV V OBIEKTAKH VNESHNEI SREDY. NORMATIVNYE MATERIALY. (MAXIMUM ALLOWABLE CONCENTRATIONS AND PRELIMINARY SAFETY LEVELS OF TOXIC SUBSTANCES IN ENVIRONMENT. STANDARDS.), , , 1978

\*\*\*\*\*

File: 17.01 LEGAL rn: 1142377

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 area : RUS rtecs no :GO6300000 type : REG

\_\_\_\_\_ |subject|specification|descriptor| -----AIR OCC MAC CLASS \_\_\_\_\_

CLV: 1.5MG/M3; TWA: 0.5MG/M3 (VAPOUR) (APPLIESTO MIXTURE OF ALL CRESOL

ISOMERS) HAZ. CLASS: II

entry date: MAY 1990 effective date: NOV1989

amendment: PDKAD\*, PREDELNO DOPUSTIMYE KONTSENTRATSII VREDNYKH

VESHCHESTV V VOZDUKHERABOCHEI ZONY (MAXIMUM ALLOWABLE CONCENTRATIONS OF HARMFUL SUBSTANCES IN OCCUPATIONAL AIR),

5147-89 , , , 1989

\*\*\*\*\*

### File: 17.01 LEGAL rn: 1301058

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

:95-48-7 : USA rtecs no :GO6300000 type : REG cas no

area

subject	descriptor	
MANUF	REQ	PRMT
USE	OCC	PRMT
SAFTY	OCC	MXL

\_\_\_\_\_\_

; Summary - THE FOLLOWING CHEMICAL IS INCLUDED ON A LIST OF CHEMICALS AND MIXTURES FOR WHICH REPORTING IS CURRENTLY REQUIRED UNDER THE TOXIC SUBSTANCES CONTROL ACT SECTION 2607A. THIS TOXIC SUBSTANCE IS SUBJECT TO PRELIMINARY ASSESSMENT INFORMATION RULES ON PRODUCT ION QUANTITIES, USES, EXPOSURES, AND ADVERSE EFFECTS. MANUFACTURERS INCLUDING IMPORTERS MUST SUBMIT A REPORT FOR THIS LISTED CHEMICAL MANUFACTURED AT EACH SITE.

entry date: OCT 1991 effective date: 1982

title: PRELIMINARY ASSESSMENT INFORMATION RULES

original: FEREAC, FEDERAL REGISTER, 47 , , 26998 , 1982

amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 712 , 30 , 1990

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#### File: 17.01 LEGAL rn: 1307093

systematic name: Phenol, 2-methyl-

common name : 0-cresol reported name :o-cresol

cas no :95-48-7 area : USA rtecs no :GO6300000 type : REG

1	-	specification	-
	AIR		RQR

; Summary - FROM A LIST OF POLLUTANTS JUDGED TO BE HAZARDOUS FOR WHICH

EMISSION STANDARDS WILL BE DEVELOPED

entry date: SEP 1991 effective date: 1985

title: CLEAN AIR ACT, 112--NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

original: FEREAC, FEDERAL REGISTER, 50 , , 46290 , 1985

amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 61 , 1 , 1990

\*\*\*\*\*

### File: 17.01 LEGAL rn: 1309466

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

cas no :95-48-7 rtecs no :G06300000 type : REG

area : USA

\_\_\_\_\_ |subject|specification|descriptor| -----CLASS | INDST | RQR AIR EMI RQR AQ EMI RQR

1000 (454); Summary - RELEASES OF THIS HAZARDOUS SUBSTANCE, IN QUANTITIES EQUAL TO OR GREATER THAN ITS REPORTABLE QUANTITY (RQ), REPORTED AS >LBS (KG) |, ARE SUBJECT TO REPORTING TO THE NATIONAL RESPONSE CENTER UNDER THE COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT. (#) - RQ IS SUBJECT TO CHANGE entry date: SEP 1991 effective date: 1990

title: CERCLA: LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES original : CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 302 ,  $\overset{\sim}{4}$  , 1990 amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 302 , 4 , 1990

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### File: 17.01 LEGAL rn: 1313249

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

rtecs no :GO6: cas no :95-48-7 area : USA :GO6300000

\_\_\_\_\_

subject | specification | descriptor | -----AQ EMI RQR
AQ GRND RQR
AQ MARIN RQR RQR

1000 (454) LBS (KG); Summary - FOR PURPOSES OF SECTION 311 OF THE CLEAN WATER ACT THE FOLLOWING HAZARDOUS SUBSTANCES IN QUANTITIES GIVEN SHALL NOT BE DISCHARGED INTO OR UPON THE NAVIGABLE WATERS OF THE UNITED STATES OR ADJOINING SHORELINES, WATERS OF THE CONTIGUOUS ZONE, OR OUTER DEEP WATERS WHICH MAY AFFECT NATURAL RESOURCES BELONGING TO THE UNITED STATES.

entry date: SEP 1991 effective date:

title: REPORTABLE QUANTITIES OF HAZARDOUS SUBSTANCES; CLEAN WATER ACT,

original: FEREAC, FEDERAL REGISTER, 51,, 34547, 1986

amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 117 , 3 , 1991

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File: 17.01 LEGAL rn: 1323081

systematic name: Phenol, 2-methyl-

common name :O-cresol

reported name :1-HYDROXY-2-METHYLBENZENE

cas no :95-48-7 rtecs no :G063 type : REG :GO6300000

: USA area

\_\_\_\_\_ subject | specification | descriptor | -----PESTI CLASS ROR MANUF PESTI PRMT FOOD ADDIT RQR PRMT

-----

CASE NAME META-CRESOL; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF ACTIVE INGREDIENTS CONTAINED IN A PRODUCT FIRST REGISTERED BEFORE NOVEMBER 1, 1984, FOR WHICH A REGISTRATION STANDARD HAS NOT BEEN ISSUED. PUBLICATION OF THIS LIST INITIATES AN ACCELERATED REREGISTRATION AND DATA C ALL-IN FOR PRODUCTS CONTAINING THE LISTED ACTIVE INGREDIENTS.

entry date: JAN 1992 effective date:

title: FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT PESTICIDES REQUIRED TO BE REREGISTERED; LIST D

original: FEREAC, FEDERAL REGISTER, 54, 204, 43388, 1989

amendment: FEREAC, FEDERAL REGISTER, 54 , 204 , 43388 , 1989

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File: 17.01 LEGAL rn: 1324066

systematic name: Phenol, 2-methyl-

common name : 0-cresol

reported name :o-cresol cas no :95-48-7

rtecs no :G06300000 type : REG

: USA area

\_\_\_\_\_\_ subject|specification|descriptor| -----AQ GRND MONI AQ GRND MXL MONIT

; Summary - THIS LIST IS REQUIRED ONLY FOR GROUND-WATER MONITORING AT RCRA LAND BASED HAZARDOUS WASTE DISPOSAL UNITS. THIS FINAL RULE WILL REQUIRE THAT AN ANALYSIS OF ALL THE CONSTITUENTS OF THIS LIST BE PERFORMED ON THE GROUND WATER TAKEN FROM WELLS SURROUNDING TH OSE UNITS. THIS ANALYSIS TAKES PLACE WHEN GROUND-WATER CONTAMINATION IS FIRST DETECTED, AND THEN AGAIN ONCE PER YEAR 40 CFR 264. WHEN A LISTED CONSTITUENT IS FOUND TO BE PRESENT A BACKGROUND VALUE MUST BE SET IN COMPLIANCE WITH 40 CFR 264.98(H)(2) UNLE SS OTHERWISE STATED.

entry date: SEP 1991 effective date:

title: LIST (PHASE 1) OF HAZARDOUS CONSTITUENTS FOR GROUND-WATER MONITORING FINAL RULE: INCLUDING MAXIMUM CONCENTRATION OF CONSTITUENT: FOR GROUNDWATER PROTECTION.

original: FEREAC, FEDERAL REGISTER, 52 , , 25947 , 1987

amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 264 , , 1990

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### File: 17.01 LEGAL rn: 1325365

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

cas no :95-48-7 area : USA rtecs no :GO6300000 type : REC

subject	specification	descriptor
SAFTY	OCC	MXL
USE	OCC	MXL

250 PPM /CRESOL/

entry date: OCT 1991 effective date: JUN1990

title: POCKET GUIDE TO CHEMICAL HAZARDS

original: XPHPAW, US PUBLIC HEALTH SERVICE PUBLICATION, 90 , 117 , 74

amendment: XPHPAW, US PUBLIC HEALTH SERVICE PUBLICATION, 90 , 117 , 74 , 1990

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### File: 17.01 LEGAL

rn: 1333010

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

rtecs no cas no :95-48-7 :GO6300000

: REG area : USA type

subject	specification	descriptor
   WASTE	+	   MPC
AQ		MPC
l ao	GRND	MPC

200.0 MG/L.. IF O-,M-, AND P-CRESOL CONCENTRATIONS CANNOT BE DIFFERENTIATED, THE TOTAL CRESOL CONCENTRATION IS USED . THE REGULATORY LEVEL OF TOTAL CRESOL IS 200 MG/L.; Summary - THIS CHEMICAL IS A CONTAMINANT CONTAINED IN WATER WHICH MAY NOT EXCEED THE GIVEN CONCENTRATION WHEN EXTRACTED BY THE PROCEDURE DESCRIBED IN 40 CFR 261 APP II. THIS APPLIES TO WASTES DISPOSED OF IN SUCH A MANNER AS TO ALLOW THE CONTAMINANTS LISTED TO LEA CH INTO GROUND WATER OR RUN OFF INTO SURFACE WATERS.

entry date: JAN 1992 effective date: 1990

title: RCRA-RESOURCE AND CONSERVATION RECOVERY ACT: MAXIMUM CONCENTRATION OF CONTAMINANTS CHARACTERISTIC OF EXTRACTION PROCESS (EP)

original: FEREAC, FEDERAL REGISTER, 55 , , 11862 , 1990 amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 261 , 24 , 1990

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### File: 17.01 LEGAL rn: 1335224

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 area : USA rtecs no :GO6300000

type : REG

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subject	specification	descriptor
SAFTY	INDST	RQR
STORE	INDST	RQR

TPQ=1,000/10,000 RQ=1,000; Summary - THE PRESENCE OF EXTREMELY HAZARDOUS SUBSTANCES IN EXCESS OF THE THRESHOLD PLANNING QUANTITY (TPQ), IN POUNDS, REQUIRES CERTAIN EMERGENCY PLANNING ACTIVITIES TO BE CONDUCTED. FOR CHEMICALS THAT ARE SOLIDS, THERE MAY BE TWO TPQ'S GIVEN. IN THESE CASES, T HE LOWER QUANTITY APPLIES FOR SOLIDS IN POWDER FORM WITH PARTICLE SIZE LESS THAN 100 MICRONS, OR IF THE SUBSTANCE IS IN SOLUTION OR IN MOLTEN FORM. OTHERWISE, THE HIGHER QUANTITY APPLIES. THESE CHEMICALS ARE ALSO SUBJECT TO REGULATION UNDER SARA 304. RELEASES OF SUBSTANCES, IN QUANTITIES EQUAL TO OR GREATER THAN THEIR REPORTABLE QUANTITY (RQ), IN POUNDS, ARE SUBJECT TO REPORTING TO THE NATIONAL RESPONSE CENTER UNDER THE COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT OF 1980.

entry date: OCT 1991 effective date:

title: SARA, SECTION 302(A) EMERGENCY PLANNING AND COMMUNITY RIGHT TO KNOW ACT; LIST OF EXTREMELY HAZARDOUS SUBSTANCES AND THEIR THRESHOLD PLANNING QUANTITIES

original : FEREAC, FEDERAL REGISTER, 52 , , 13395 , 1987 amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 355 , , 1990

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File: 17.01 LEGAL rn: 1336119

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 rtecs no :G06300000

area : USA type : REG

subject	specification	descriptor
	+	+
AIR	EMI	RQR
SOIL	EMI	RQR
AQ	EMI	RQR
MANUF	EMI	RQR

CLASSIFICATION(SIC) CODES 20-39 ONLY).

; Summary - FACILITIES THAT EXCEEDED A MANUFACTURING, IMPORTATION, OR PROCESSING THRESHOLD OF 25,000 LBS OR THE USE OF 10,000 LBS FOR THIS CHEMICAL MUST REPORT TO EPA ANY RELEASES OF THE CHEMICAL (OR CATEGORY CHEMICAL) TO AIR, LAND, WATER, POTW, UNDERGROUND INJECTIO N, OR OFF SITE TRANSFER. THIS REGULATION COVERS STANDARD INDUSTRIAL

entry date: OCT 1991 effective date: 1

title: SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT, TITLE III. EPCRA SECTION 313 LIST OF TOXIC SUBSTANCES

original : CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 372 , 65 , 1988 amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 372 , 65 , 1988

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File: 17.01 LEGAL rn: 1340920

systematic name:Phenol,2-methylcommon name :O-cresol

reported name :o-cresol

cas no :95-48-7 area : USA rtecs no :GO6300000 type : REC

\_\_\_\_\_ |subject|specification|descriptor| -----AIR OCC TLV

\_\_\_\_\_

Time Weighted Avg (TWA) 5 ppm, 22 MG/M3, skin /Cresol, all isomers/; Summary - THIS THRESHOLD LIMIT VALUE IS INTENDED FOR USE IN THE PRACTICE OF INDUSTRIAL HYGIENE AS A GUIDELINE OR RECOMMENDATION IN THE CONTROL OF POTENTIAL HEALTH HAZARDS.

effective date: 1989 entry date: DEC 1991

title: THRESHOLD LIMIT VALUES

original : ACGIH\*, AMERICAN CONFERENCE OF GOVERNMENT INDUSTRIAL

HYGIENISTS, , , 11 , 1989

amendment: ACGIH\*, AMERICAN CONFERENCE OF GOVERNMENT INDUSTRIAL

HYGIENISTS, , , 11 , 1991

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File: 17.01 LEGAL rn: 1345062

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

rtecs no :GO6300000 type : REG cas no :95-48-7 area : USA

|subject|specification|descriptor| -----MONIT | RQR

\_\_\_\_\_ ; Summary - THIS IS A CHEMICAL OR MIXTURE FOR WHICH REPORTING IS CURRENTLY REQUIRED UNDER THE TOXIC SUBSTANCE CONTROL ACT HEALTH AND SAFETY STUDIES SECTION 2607D. PERSONS WHO CURRENTLY MANUFACTURE OR PROCESS CHEMICAL SUBSTANCES OR MIXTURES FOR COMMERCIAL PURPOSES, THOSE WHO PROPOSE TO DO SO, AND THOSE WHO ARE NOT CURRENTLY INVOLVED WITH A LISTED CHEMICAL BUT WHO MANUFACTURED OR PROCESSED IT OR PROPOSED TO DO SO ANY TIME DURING THE TEN YEAR PERIOD PRIOR TO THE TIME IT BECAME LISTED MUST SUBMIT TO THE ADMINISTRATOR OF THE U.S. EPA STUDIES OR LISTS OF HEALTH AND SAFETY STUDIES CONDUCTED ON THIS SUBSTANCE FOR EVALUATION.

effective date: 1986 entry date: OCT 1991

title: HEALTH AND SAFETY DATA REPORTING RULES SECTION 8(D) original : FEREAC, FEDERAL REGISTER, 51 , , 32726 , 1986

amendment: CFRUS\*, CODE OF FEDERAL REGULATIONS, 40 , 716 , 120 , 1990

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File: 17.01 LEGAL rn: 1405109

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

cas no :95-48-7 area : EEC rtecs no :GO6300000 type : REG

|subject|specification|descriptor| -----CLASS | CLASS | RQR LABEL

PACK | RQR -----

CLASS: T - TOXIC; TOXIC IN CONTACT WITH SKIN AND IF SWALLOWED (R

C - CORROSIVE; CAUSES BURNS (R 34). LABEL: T - TOXIC; TOXIC IN CONTACT WITH SKIN AND IF SWALLOWED (R 24/25); CAUSES BURNS (R 34); (KEEP LOCKED UP AND OUT OF THE REACH OF CHILDREN (S 1/2)); WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE PROTECTION (S 36/37/39); IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE) (S 45). CLASSIFICATION OF PREPARATIONS CONTAINING THE SUBSTANCE IN CONCENTRATION RANGE: ABOVE 5%: T - TOXIC; TOXIC IN CONTACT WITH SKIN AND IF SWALLOWED (R 24/25); CAUSES BURNS (R 34). FROM 1% TO 5%: XN - HARMFUL; HARMFUL IN CONTACT WITH SKIN AND IF SWALLOWED (R 21/22); IRRITATING TO EYES AND SKIN (R 36/38). APPLIES TO ALL CRESOL ISOMERS. IT MUST BE STATED ON THE LABEL WHETHER IT IS A SPECIFIC ISOMER OR A MIXTURE OF ISOMERS.

entry date: AUG 1994 effective date: JAN1994

title: COUNCIL DIRECTIVE 67/548/EEC OF 27 JUNE 1967 ON THE APROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES

original: OJEC\*\*, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, 196, ,1 , 1967

amendment: OJEC\*\*, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L 13 , , 1 , 1994

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## File: 17.01 LEGAL

rn: 1407221

systematic name: Phenol, 2-methyl-

common name :O-cresol reported name :o-cresol

:95-48-7 rtecs no :GO6300000 cas no

area : EEC : REG type

|subject|specification|descriptor| -----AIR OCC ILV \_\_\_\_\_

INDICATVE LIMIT VALUE: 22 MG/M3 OF AIR AT 20 C AND 101.3 KPA (5 PPM) AS MEASURED OR CALCULATED IN RELATION TO A REFERENCE PERIOD OF EIGHT HOURS (WITH REGARD TO ESTABLISHING THE LIMIT VALUES REFFERED TO IN ARTICLE 4(4)(B) OF DIRECTIVE 80/1107/EEC) (APPLIES TO ALL CRESOL ISOMERS). entry date: AUG 1995 effective date: 01JAN1994

title: COMMISSION DIRECTIVE OF 29 MAY 1991 ON ESTABLISHING INDICATIVE LIMIT VALUES BY IMPLEMENTING COUNCIL DIRECTIVE 80/1107/EEC ON THE PROTECTION OF WORKERS FROM RISKS RELATED TO EXPOSURE TO CHEMICAL, PHYSICAL AND BIOLOGICAL AGENTS AT WORK (91/322/EEC)

original : OJEC\*\*, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L172 , , 22 , 1991

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# File: 17.01 LEGAL

rn: 1408365

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

: REG :95-48-7 rtecs no :GO6300000 cas no

: EEC type

|subject|specification|descriptor|

	+	
FOOD		RQR
GOODS	İ	MXL
GOODS		PRMT

\_\_\_\_\_\_ THE SUBSTANCE IS INCLUDED IN THE LIST OF AUTHORIZED MONOMERS AND OTHER STARTING SUBSTANCES, WHICH SHALL BE USED FOR THE MANUFACTURE OF PLASTICS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS. THE USE OF THE SUBSTANCE IS SUBJECT TO THE RESTRICTIONS SPECIFIED THEREIN. PLASTIC MATERIALS AND ARTICLES SHALL NOT TRANSFER THEIR CONSTITUENTS TO FOODSTUFFS IN OUANTITIES EXCEEDING 10MG/DM2 OF SURFACE AREA OF MATERIAL OR ARTICLE OR 60 MG/KG OF FOODSTUFFS IN THE SPECIFIED CASES. VERIFICATION OF COMPLIANCE WITH THE MIGRATION LIMITS SHALL BE CARRIED OUT IN ACCORDANCE WITH DIRECTIVES 82/711/EEC AND 85/572/EEC. V? UE: 22 MG/M3 OF AIR AT 20 C AND 101.3 KPA (5 PPM) AS MEASURED OR CALCULATED IN RELATION TO A REFERENCE PERIOD OF EIGHT HOURS (WITH REGARD TO ESTABLISHING THE LIMIT VALUES REFFERED TO IN ARTICLE 4(4)(B) OF DIRECTIVE 80/1107/EEC) (APPLIES TO ALL CRESOL

entry date: AUG 1995 entry date: SEP 1995

ISOMERS).

effective date: 01JAN1991

title: COMMISSION DIRECTIVE OF 23 FEBRUARY 1990 RELATING TO PLASTICS MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS (90/128/EEC)

original: OJEC\*\*, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L75, ,19 , 1990

amendment: OJEC\*\*, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L90 , ,26 , 1993

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### File: 17.01 LEGAL

rn: 1600206

systematic name: Phenol, 2-methyl-

common name :0-cresol reported name :o-cresol

cas no :95-48-7 rtecs no :G06300000 type : REC

: UN area

\_\_\_\_\_ |subject|specification|descriptor| ----+-----LABEL PACK |

HAZARD CLASS: 6.1 = TOXIC SUBSTANCE. SUBSIDIARY RISK: 8 = CORROSIVE SUBSTANCE. PACKING GROUP: II = MEDIUM DANGER. PACKING METHOD: M. (APPLIES TO O-, M- AND P-CRESOLS). UN NO. 2076.

entry date: SEP 1994 effective date: 1993

title: RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS amendment: !UNTDG\*, UN TRANSPORT OF DANGEROUS GOODS, RECOMMENDATION PREPARED BY THE COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS, , , 19 , 1993

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### File: 17.01 LEGAL rn: 1604122

systematic name: Phenol, 2-methyl-

common name : O-cresol reported name :o-cresol

rtecs no :G06300000 cas no :95-48-7

area	: IMO		type	: REG	
subject	specification	descriptor			
TRNSP	+   MARIN   EMI	+    RQR   RQR			

Category A substance (substance which is bioaccumulated and liable to produce a hazardto aquatic life or human health or which is highly toxic to aquatic life): discharge into the sea of this substance, of ballast water, tank washings of other residues containing it shall be probihited. If tanks containing the substance or mixtures thereof are to be washed, the resulting residues shall be discharged to a reception facility until the concentration of the effluent to such a facility is at or below 0.1% by weight (0.05% within special areas) and until the the tank is empty. Technological requirements prescribe equipments and designs that must be present on the tankers as well as port facilities for receiving residues or mixturescontaining the regulated substance.

Technicalassistance for training of scientific and technical personnel shall be promoted where requested by the Parties to the Convention. entry date: SEP 1994

title: International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78)

original : IMODC\*, , , , 1992

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File: 17.01 LEGAL rn: 1605502

systematic name: Phenol, 2-methyl-

common name :O-cresol reported name :o-cresol

rtecs no :GU63 : REC cas no :95-48-7 :GO6300000

area : IMO

\_\_\_\_\_ |subject|specification|descriptor| -----TRNSP | MARIN | CLASS LABEL PACK |

\_\_\_\_\_'

HAZARD CLASS: 6.1 = POISONOUS SUBSTANCE. P = MARINE POLLUTANT. PACKING GROUP: II = MEDIUM DANGER (I=GREAT DANGER, III=MINOR DANGER). (APPLIES TO O-, M- AND P-CRESOLS, LIQUID AND SOLID). UN NO. 2076. entry date: SEP 1994 effective date: 1991

title: INTERNATIONAL MARITIME DANGEROUS GOODS CODE (IMDG CODE) amendment: IMCOC\*, IMO DANGEROUS GOODS CODE, RECOMMENDATION PREPARED BY THE MARITIME SAFETY COMMITTEE, 26-91 , , 10054 , 1991