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29 JAN. 2002

Date:
Our ref.: 98/2245-30 /354.3
Your ref.:
Contact person: Bjørg Fjeld

Notification of Final Regulatory Action

Please find enclosed a notification from Norway concerning final regulatory action related to short chain chlorinated paraffins. The notification is made in line with Article 5 of the Rotterdam Convention and its interim procedure.

This notification will also be sent to the Secretariat via e-mail.

Yours sincerely,

Signe Næmdal
Signe Næmdal
Head of section

Enclosure: Notification form for final regulatory action related to short chain chlorinated paraffins.

UNEP Chemicals	
Date Received :	1.2.02
File no / name :	PC
For action :	
Cc :	



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

IMPORTANT: See instructions before filling in the form

COUNTRY: NORWAY

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL		
1.1	Common name	Short Chain Chlorinated Paraffins (SCCP)
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	Alkanes, C ₁₀₋₁₃ , chloro, Chlorinated paraffins with a chlorination degree of more than 48 % by weight.
1.3	Trade names and names of preparations	
1.4	Code numbers	
1.4.1	CAS number	85535-84-8
1.4.2	Harmonized System customs code	
1.4.3	Other numbers (specify the numbering system)	

1.5 Indication regarding previous notification on this chemical, if any	
1.5.1	<input checked="" type="checkbox"/> This is a first time notification of final regulatory action on this chemical.
1.5.2	<input type="checkbox"/> This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____
	<input type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____	

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
EU - classification in accordance with Directive 67/548/EC (Annex I, 25. ATP)	Health: Symbol Xn, Carc. Cat 3. Risk phrase: R40: Limited evidence of a carcinogenic effect Environment: Symbol N: Dangerous for the environment Risk phrase: R50-53: Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
Other classification systems	

1.7 Use or uses of the chemical	
1.7.1	<input type="checkbox"/> Pesticide Describe the uses of the chemical as a pesticide in your country: Not relevant
1.7.2	<input checked="" type="checkbox"/> Industrial Describe the industrial uses of the chemical in your country: SCCPs have in Norway mainly been used as softeners in paints, plastics, fillers and coatings, as flame inhibitors in rubber, plastics and textiles, and as additives in other chemical substances and products. There has also been limited use in metal working fluids as well as in certain lubricants and car care products. SCCP is also used in leather processing, however, this is not known to be the case in Norway.

1.8 Properties	
1.8.1	Description of physico-chemical properties of the chemical Identity: clear/yellowish viscous liquid Formula $C_xH_{(2x-y+2)}Cl_y$, where $x = 10-13$ and $y = 1-13$ Chemical name: Alkanes, C_{10-13} , chloro Chemical type CAS number : 85535-84-8 Molecular weight : 320 - 500 Solubility: 0,15 - 0,47 mg/l (59 % Cl) at 20 °C logKow : 4,39 - 8,01 (dependant on chlorine content) BCF: 1000 - 50 000 Vapour pressure : 0, 021 Pa at 40 °C (50% Cl) Melting point: Not relevant Boiling point: > 200°C at NTP Dissociation constant: Henry's law constant:

1.8.2 Description of toxicological properties of the chemical

Acute toxicity: Limited information available from animal studies indicate that SCCPs are of low acute toxicity. No toxicity occurred in rats following 1 hour exposure to a vapour or aerosol of 3300 mg/ m³ or with a dermal dose of 2,8 g/kg. Some signs of systemic toxicity with oral doses up to 13 g/kg in rats and 27 g/kg in mice were seen. The nature and degree of effects were independent of degree of chlorination.

2. Repeated exposure:

The liver and thyroid were identified as target organs in oral studies in rats and mice, however, the thyroid effects seen in rats and mice are considered unlikely to be relevant to human health. Other signs of toxicity, such as reduction in body weight gain and increase in kidney weight, were observed in several 14- and 90-days studies in rats and mice. NOAELs for effects considered relevant to human health of 100 and 1000 mg/kg/day were identified in rats and mice respectively.

3. Effects on reproduction:

There are no data available on fertility in animals, however, no changes were seen in the reproductive organs in rats and mice treated for 13 weeks with up to 5000 and 2000 mg/kg/day respectively. In a study in rats chlorinated paraffins produced developmental effects at a dose which also caused maternal toxicity (2000 mg/kg), but no developmental effects at lower doses (500 mg/kg and below). For developmental effects a NOAEL of 500 mg/kg/day has been established.

4. Mutagenicity:

Overall, the data available (and a consideration of the generally unreactive nature of the SCCPs), indicate that SCCPs as a group are not mutagenic.

5. Carcinogenicity:

In rodent studies the chlorinated paraffins tested produced toxicologically significant, dose-related increases in the incidence of several tumor types, e.g. in the liver, thyroid and kidney. The substance is classified as carcinogenic in category 3, i.e. substances that cause concern for man owing to possible carcinogenic effects, but in respect of which the available information is not adequate for making a satisfactory assessment.

7. Effects on human health:

There is no information available on studies in humans regarding acute toxicity, reprotoxicity, mutagenicity and carcinogenicity.

References:

- 1) "Short Chain Chlorinated Paraffins, a *Materialflow analysis*", .Norwegian Pollution Control Authority.
- 2) "OSPAR Background Document on Short Chain Chlorinated Paraffins"
- 3) "EU risk assessment on CAS no 85535-84-8, alkanes, C₁₀₋₁₃, chloro"

1.8.3 Description of ecotoxicological properties of the chemical

Fish: SCCPs are of relatively low acute toxicity to fish with 48 and 96 hours LC₅₀ values in excess of 100 mg/l. A 60 days **chronic** toxicity study shows a LC₅₀ of 0.34 mg/l, and NOECs of < 0,040 and 0.28 mg/l for rainbow trout and sheepshead minnow respectively are registered.

Invertebrates:

24 hours EC50 s for Daphnids range from 0,3 to 11,1 mg/l. In a multigeneration study with *Daphnia magna* the lowest NOEC ("no observed effect concentration") identified was 0,005 mg/l. With respect to chronic toxicity *Daphnia magna* was the most sensitive aquatic species tested.

<p>Bees:</p> <p>Birds: In a reproduction study with mallard duck slight effects on reproduction were seen at 1000 mg/kg, the highest concentration without adverse effects was 166 mg/kg food</p> <p><u>References</u> 1) "Short Chain Chlorinated Paraffins, a <i>Materialflow analysis</i>", .Norwegian Pollution Control Authority. 2) "OSPAR Background Document on Short Chain Chlorinated Paraffins" 3) "EU risk assessment on CAS no 85535-84-8, alkanes, C₁₀₋₁₃, chloro"</p>

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION	
2.1	The chemical is: <input checked="" type="checkbox"/> banned OR <input type="checkbox"/> severely restricted
2.2	Information specific to the final regulatory action
2.2.1	Summary of the final regulatory action Production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0,1 % SCCP is prohibited .
2.2.2	Reference to the regulatory document "Regulation Governing Short Chain Chlorinated Paraffins", laid down by Ministry of the Environment 13 December 2000 with a legal basis in Act no 79 of 11 June 1976 relating to product control, section 4.
2.2.3	Date of entry into force of the final regulatory action The regulation entered into force 01.01.2001. However, stock items imported or produced before 01.01.2001 may be sold and used until 01.01.2002. As stated i OSPAR decision 95/1, there is a transition period until 1 January 2005 for conveyor belts used in the mining industry and for sealing materials in dams containing SCCP. However, such applications are not relevant for the situation in Norway.

2.3	Was the final regulatory action based on a risk or hazard evaluation?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give information on such evaluation	SCCPs are very toxic to water living organisms, they degrade slowly in the environment and have a high potential for bioaccumulation. This, together with the potential for long range transport via air and water, confirmed by monitoring data, give rise to serious concerns for long term effects in the aquatic environment. SCCP is also classified as a category 3 carcinogen, i.e. there is limited evidence of carcinogenic effects.
	Reference to the relevant documentation	

- 1) "Short Chain Chlorinated Paraffins, a *Materialflow analysis*", Norwegian Pollution Control Authority.
- 2) "OSPAR Background Document on Short Chain Chlorinated Paraffins"
- 3) "EU risk assessment on CAS no 85535-84-8, alkanes, C₁₀₋₁₃, chloro"

2.4	Reasons for the final regulatory action	
2.4.1	Is the reason for the final regulatory action relevant to the human health?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.4.2	Is the reason for the final regulatory action relevant to the environment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	If yes, give summary of the known hazards and risks to the environment	
	SCCPs are very toxic to aquatic organisms, especially daphnids. They degrade slowly in the environment and have a high potential for bioaccumulation. Their negative long term effects in the aquatic environment, the risk of secondary poisoning of predators through the food chain, and their potential for long range transport via air and water give rise to serious concerns.	
	Reference to the relevant documentation	
	<ol style="list-style-type: none"> 1) "Short Chain Chlorinated Paraffins, a <i>Materialflow analysis</i>", Norwegian Pollution Control Authority. 2) "OSPAR Background Document on Short Chain Chlorinated Paraffins" 3) "EU risk assessment on CAS no 85535-84-8, alkanes, C₁₀₋₁₃, chloro" 	
	Expected effect of the final regulatory action	
	Reduction of risk to the aquatic environment	

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Industrial
	Use or uses prohibited by the final regulatory action	
	Practically all known uses	
	Use or uses that remain allowed	
	Use for research and analytical purposes is still allowed	

2.5.2	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	

Not relevant
Formulation(s) and use or uses that remain allowed
Not relevant

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced	0	
Imported	24,040	1998
Exported	8,416	1998
Used	15,624	1998

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

2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action

2.7.2	Information on alternatives and their relative risks
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Ministry of Environment (issuing) Norwegian Pollution Control Authority (enforcing)
Address	Norwegian Pollution Control Authority PO Box 8100 Dep N-0032 Oslo Norway
Telephone	+ 47 22 57 34 00
Telefax	+ 47 22 67 67 06
E-mail address	Postmottak@sft.no
Designated National Authority	
Institution	Norwegian Pollution Control Authority Section for Chemicals and Metallurgical Industry
Address	PO Box 8100 Dep N - 0032 Oslo Norway

Name of person in charge	Bjørg Fjeld
Position of person in charge	Senior Adviser
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Oslo 01.02.2002.

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