



EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENVIRONMENT
Directorate C – Environment and Health
ENV.C.3 - Chemicals

Brussels, 31.05.2002
ENV.C.3/D(02) 430297

Mr. Van der Graaff
Interim Secretariat for the Rotterdam
Convention, Plant Protection Service
Plant Production and Protection
Division, FAO
Viale delle Terme di Caracalla
IT- 00100 Rome

Dear Mr Van der Graaff,

In line with Article 5 of the Rotterdam Convention and its interim procedure, I am pleased to send you herewith a European Community notification concerning a final regulatory action in respect of nitrofen.

A copy of the completed notification form is also being sent to the secretariat by Email.

Yours sincerely,

SIGNED
Julian FOLEY

Cc: Mr Willis, UNEP

BC: E. Hellsten, R. Donkers, K Berend, P. Bombay, J. Garcia Burgues, (DG ENV)
R. Schulte-Braucks, U. Kowalski, (DG ENTR)
G. Vollmer, E. Berggren, M. Nichelatti, J. Sala Benito, (DG JRC)
L. Smeets (DG SANCO)
L. Ström, (DG SJ)
M. Debois (DG DEV)
EU and EEA DNA for Regulation 2455/92
C. Steinland (Efta)

(Without enclosures)

I U C L I D

D a t a s e t

Existing Chemical	Substance ID: 1836-75-5
CAS No.	1836-75-5
EINECS Name	nitrofen
EINECS No.	217-406-0
Molecular Formula	C12H7Cl2NO3

Dataset created by: EUROPEAN COMMISSION - European Chemicals Bureau

This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.

The data have not undergone any evaluation by the European Commission.

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European Chemicals Bureau



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

IMPORTANT: See instructions before filling in the form

COUNTRY: European Community
(Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and United Kingdom)

PART I: PROPERTIES, IDENTIFICATION AND USES

1. IDENTITY OF CHEMICAL	
1.1	Common name Nitrofen
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists Nitrofen IUPAC: 2,4-dichloro-4'-nitrodiphenyl ether CAS: 2,4-dichloro-1-(4-nitrophenoxy)benzene
1.3	Trade names and names of preparations Tok-2, Niclophen, Mezotox®; Niclofen®; NIP®; NIPDIA®; NIPQ-P; Nitrafen®; Nitraphen®; Nitrochlor®; Tok®; Tok-E25®; TokWP-50®; Tokkorn®; Trizilin®; FW-925 (WHO/FAO, 1996), Preparation 125; Tok E; Tok E40; Trazalex (Hoechst AG)
1.4	Code numbers
1.4.1	CAS number 1836-75-5
1.4.2	Harmonized System Customs Code 3808 30 27 90
1.4.3	Other numbers (specify the numbering system) EU N°: 217-406-0 KES: KN8400000

PLEASE RETURN THE COMPLETED FORM TO:

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

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

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

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

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

1.5 Indication regarding previous notification on this chemical, if any	
1.5.1	<input 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 checked="" type="checkbox"/> This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: 11/8/93	

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	Hazard class
IARC Classification in the EU in accordance with Directive 67/548/EEC	Possible human carcinogen (group 2B) T (toxic), R22 (harmful if swallowed) R45 (may cause cancer, carcinogenic cat. 2), R 61 (May cause harm to the unborn child, toxic for reproduction cat. 2); N (dangerous for the environment), R50-53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).
Other classification systems	Hazard class

1.7 Use or uses of the chemical	
1.7.1	<input checked="" type="checkbox"/> Pesticide Describe the uses of the chemical as a pesticide in your country: _____ The chemical is a pre- and post-emergence herbicide used on many vegetables, a number of broad-leaved and grass weeds, cereals, rice, sugar beet, some ornamentals, broccoli, cauliflower, cabbage, brussel sprouts, onions, garlic and celery. It was also used in nurseries for roses and chrysanthemums.
1.7.2	<input type="checkbox"/> Industrial Describe the industrial uses of the chemical in your country: _____ Not used.

1.8 Properties	
1.8.1	Description of physico-chemical properties of the chemical
	<p>Form Solid</p> <p>Purity > 98 %</p> <p>Impurities para-chloronitrobenzene, bis(para-nitrophenyl)ether, 2,4-dichloro-2,2'-dinitrophenyl ether, 2-chloro-4'-nitrodiphenyl ether and 4-chloro-4'-nitrophenyl ether</p> <p>Formula C₁₂H₇Cl₂NO₃</p> <p>Molecular weight 284.1</p> <p>Melting point 70-71 °C</p> <p>Boiling point 368 °C at 1013 hPa</p> <p>Relative density 1.377 g/cm³ at 80 °C</p> <p>Vapor pressure 10⁻⁶ hPa at 40°C</p> <p>Henry's law constant 5.7 x 10⁻⁵ Pa x m³/mol</p> <p>Solubility in water 0.5 mg/l at 20 °C and pH 7</p> <p>Solubility in organic solvents: DMSO: ≥100 mg/l (21 °C) 95% ethanol: 5-10 mg/l (21 °C) Acetone: ≥100 mg/l (21 °C) Benzene: 2000 mg/kg (20 °C) n-Hexane: 280 mg/kg (20 °C)</p> <p>Partition coefficient (log Pow): 5.5 (calculated value)</p> <p>Flash point: > 200 °C</p> <p>Photodegradation in air (DT₅₀) 64.3 hours (conc. of sensitizer OH: 15 x 10⁵ molecules/cm³) 3.4 days (conc. of sensitizer OH: 5 x 10⁵ molecules/cm³)</p> <p>IUCLID data set, Ed.2000 (copy attached) and data base (HSDB n°1578, NTP)</p>

1.8.2 Description of toxicological properties of the chemical	
	<p>Properties and lack of data considered in the hazard assessment:</p> <ul style="list-style-type: none"> - Acute oral toxicity: LD₅₀ (rat) = 410 mg/kg bw - Nitrofen is rapidly absorbed through the skin from solvent-based formulations. - Nitrofen is carcinogenic to rats (pancreas) and mice (liver). - NOAEL of nitrofen for developmental toxicity in rats is very low (< 1 mg/kg) - Medical data: Agricultural workers exposed to nitrofen for prolonged periods show haematological parameters modification. Chronic occupational exposure without protection results in central nervous system disturbances, anaemia, raised temperature, decreased body weight, fatigue, contact dermatitis. <p>IUCLID Data Set, Ed. 2000 (copy attached) and data base HSDB n°1578. European Commission, report of the Scientific Committee for Pesticides (Directorate-General Agriculture, EUR 10211, 1985) (Copy attached)</p>

1.8.3 Description of ecotoxicological properties of the chemical	
	<p>a) <u>Fate and behaviour:</u></p> <p>Nitrofen strongly adsorbs to soil and sediments. Degradation in aerobic soils ranges from 10 to 99 % after 40 days.. The potential dietary intake is low.</p> <p>Nitrofen is inherently biodegradable.</p> <p>b) <u>Ecotoxicity:</u></p> <ul style="list-style-type: none"> - Highly bioaccumulative - High toxicity to aquatic organisms: LC₅₀ (fish) = 0.75-2.5 mg/l, <p>IUCLID Data Set, Ed. 2000 (copy attached). Data base HSDB n°1578. European Commission, report of the Scientific Committee for Pesticides (Directorate-General Agriculture, EUR 10211, 1985) (Copy attached)</p>

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 It is prohibited to place on the market or use plant protection products containing nitrofen. The authorisations for plant protection products containing nitrofen had to be withdrawn from the 1 st January 1988 according to Council Directive 87/181/EEC of 9 March 1987.
2.2.2	Reference to the regulatory document Council Directive 87/181/EEC of 09/03/1987 amending the Annex to Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances (Official Journal of the European Community L071 of 14/03/1987, p.33) (copy attached).
2.2.3	Date of entry into force of the final regulatory action 01/01/1988

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 It has been established that the use of nitrofen as a plant protection product, in particular as herbicide, is likely to give rise to harmful effects on human and animal health.
	Reference to the relevant documentation Directive 87/181/EEC of 9 March 1987 and report of the Scientific Committee for Pesticides (Directorate-General Agriculture, EUR 10211, 1985) (Copy attached)

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 checked="" type="checkbox"/> Yes <input 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 There is sufficient evidence to provide a strong presumption that human exposure to nitrofen may result in the development of cancer.
	Reference to the relevant documentation Data base HSDB n°1578 and report of the Scientific Committee for Pesticides (Directorate-General Agriculture, EUR 10211, 1985) (Copy attached)
	Expected effect of the final regulatory action Complete risk reduction for plant protection use.

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 Hazard to non-target organisms
	Reference to the relevant documentation Data base HSDB n°1578
	Expected effect of the final regulatory action

	Complete risk reduction for human and animal health during plant protection uses.
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2.5 Category or categories where the final regulatory action has been taken											
2.5.1	<table border="1"> <tr> <td>Final regulatory action has been taken for the chemical category</td> <td><input type="checkbox"/> Industrial</td> </tr> <tr> <td>Use or uses prohibited by the final regulatory action</td> <td></td> </tr> <tr> <td>Not relevant.</td> <td></td> </tr> <tr> <td>Use or uses that remain allowed</td> <td></td> </tr> <tr> <td>Not relevant.</td> <td></td> </tr> </table>	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Industrial	Use or uses prohibited by the final regulatory action		Not relevant.		Use or uses that remain allowed		Not relevant.	
Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Industrial										
Use or uses prohibited by the final regulatory action											
Not relevant.											
Use or uses that remain allowed											
Not relevant.											

2.5.2	<table border="1"> <tr> <td>Final regulatory action has been taken for the chemical category</td> <td><input checked="" type="checkbox"/> Pesticide</td> </tr> <tr> <td>Formulation(s) and use or uses prohibited by the final regulatory action</td> <td></td> </tr> <tr> <td>Placing on the market and use of all plant protection products containing nitrofen.</td> <td></td> </tr> <tr> <td>Formulation(s) and use or uses that remain allowed</td> <td></td> </tr> <tr> <td>none</td> <td></td> </tr> </table>	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide	Formulation(s) and use or uses prohibited by the final regulatory action		Placing on the market and use of all plant protection products containing nitrofen.		Formulation(s) and use or uses that remain allowed		none	
Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide										
Formulation(s) and use or uses prohibited by the final regulatory action											
Placing on the market and use of all plant protection products containing nitrofen.											
Formulation(s) and use or uses that remain allowed											
none											

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced	Not available.	
Imported	Not available	
Exported	Not available	
Used	Not available	

2.6 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions	
	General health problem in states where the substance is used as a plant protection product. Protection of the environment.

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	European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Telephone	+322 299 48 60
Telefax	+322 296 69 95
E-mail address	klaus.berend@cec.eu.int
Designated National Authority	
Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Name of person in charge	Klaus BEREND
Position of person in charge	Administrator
Telephone	+322 299 48 60
Telefax	+322 296 69 95
E-mail address	klaus.berend@cec.eu.int

Date, signature of DNA and official seal: _____

387L0181

Council Directive 87/181/EEC of 9 March 1987 amending the Annex to Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances

Official Journal L 071 , 14/03/1987 p. 0033 - 0033

Finnish special edition....: Chapter 3 Volume 22 p. 240

Swedish special edition....: Chapter 3 Volume 22 p. 240

Text:

COUNCIL DIRECTIVE

of 9 March 1987

amending the Annex to Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances

(87/181/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (1), as last amended by Directive 86/355/EEC (2), and in particular Article 6 (3) thereof,

Having regard to the proposal from the Commission,

Whereas that Directive provides for the contents of the Annex to be regularly amended to take account of the developments of scientific and technical knowledge;

Whereas it has been established that the use of nitrofen as a plant protection product, in particular as a herbicide, is likely to give rise to harmful effects on human and animal health;

Whereas it has also been established that the uses of 1,2-dibromoethane and 1,2-dichloroethane as plant protection products, in particular to fumigate plants and soil, are likely to give rise to harmful effects on human and animal health as well as unreasonable adverse influence on the environment,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In the Annex to Directive 79/117/EEC the words 'C. Ethylene oxide' are replaced by:

'C. Other compounds

1. Ethylene oxide'

and the following entries added:

2. Nitrofen

3. 1,2-Dibromoethane

4. 1,2-Dichloroethane'

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than:

- 1 January 1988 in respect of nitrofen and 1,2-dibromoethane,

- 1 June 1989 in respect of 1,2-dichloroethane.

They shall immediately inform the Commission thereof.

Article 3

This Directive is addressed to all Member States.

Done at Brussels, 9 March 1987.

For the Council

The President

M. EYSKENS

(1) OJ No L 33, 8. 2. 1979, p. 36.

(2) OJ No L 212, 2. 8. 1986, p. 33.

End of the document