



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

- 5 -07- 2001

Brussels,  
D (01) 430318

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 Graaf,

In line with Article 5 of the Rotterdam Convention and its interim procedure, I am pleased to send you herewith European Community notifications concerning final regulatory actions related to DNOC and dinoterb respectively.

These regulatory actions have been taken within the framework of an ongoing evaluation programme under Council Directive 91/414/EC concerning the placing of plant protection products on the market. I am enclosing a copy of that Directive, together with a short explanatory note about its practical application.

As can be seen from the notifications and supporting papers, the regulatory actions were taken on the basis of risk evaluations that took into account Community patterns of use and environmental conditions. These assessments were based on data generated according to scientifically recognised methods and were conducted according to generally accepted scientific principles and procedures.

I hope that this background information is helpful. However if you have any questions on this material or the notifications, please do not hesitate to let me know.

UNEP Chemicals	
Date Received :	16.7.01
File no / name :	PC
For action :	
Cc :	

In view of the discussion at the last meeting of the interim Chemical Review Committee (UNEP/FAO/PIC/ICRC.2/11, paragraph 43), I should be grateful if you would forward a copy of the DNOC notification to the Designated National Authority for Peru for information.

Yours sincerely,



Julian FOLEY

Cc: Mr Willis, UNEP



**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**

<b>1. IDENTITY OF CHEMICAL</b>		
1.1	Common name	Dinoterb
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	2-tert-butyl-4,6-dinitrophenol (IUPAC) 2-(1,1-dimethylethyl)-4,6-dinitrophenol (CAS)
1.3	Trade names and names of preparations	Herbogil liquid, Tolkan V, Tolkan S
1.4	Code numbers	
1.4.1	CAS number	1420-07-1
1.4.2	Harmonized System customs code	2908.90 - (ISO) 3808.30 - (DNTBP), put as insecticide and herbicide. 3808.30 - put as herbicide 3808.30 - -acetate, put as acaricide and herbicide.
1.4.3	Other numbers (specify the numbering system)	EEC : 609-030-004 CIPAC : 238 EINECS : 215-813-8
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.	

**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

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
Classification in the EU in accordance with Directive 67/548/EEC (Annex I)	T+ (very toxic). R28 (very toxic if swallowed). T (toxic). R24 (toxic in contact with skin). T (toxic, reproduction cat.2). R61 (may cause harm to the unborn child). 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  Pesticide

Describe the uses of the chemical as a pesticide in your country:

Used as post emergence herbicide on maize, beans, peas, potatoes and sweet corn.

1.7.2  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

<b>Identity</b>	Yellow crystals (Purity $\geq$ 99 %)
<b>Formula</b>	$C_{10}H_{12}N_2O_5$
<b>Chemical type</b>	dinitrophenol
<b>Molecular weight</b>	240.2
<b>Melting point</b>	127.2°C
<b>Boiling point</b>	decomposition above 222°C
<b>Relative density</b>	0.705
<b>Vapor pressure</b>	$0.97 \times 10^{-3}$ Pa at 20°C
<b>Henry's law constant</b>	$10 \times 10^{-4}$ Pa $\times$ m <sup>3</sup> /mol at pH7
<b>Solubility in water</b>	2.95 mg/l at pH4 230 mg/l at pH 7 550 mg/l at pH 9
<b>Solubility in organic solvents at 25 °C:</b>	n-heptane : 9 g/kg isopropanol : 9 g/kg xylene : 200 g/kg acetone : 190 g/kg ethyl acetate : 130 g/kg
<b>Partition coefficient (log Pow)</b>	3.46 at pH4 20°C 1.91 at pH7 1.57 at pH10
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	stable at pH 5 and 9 at 22°C
<b>Photostability (DT<sub>50</sub>)</b>	14-18 days in water
<b>Dissociation constant</b>	pKa = 5.0 at 20°C

Full Report on dinoterb (ECCO-Team, 1348/ ECCO/BBA/97 of 14 April 1997).

<b>1.8.2</b>	<b>Description of toxicological properties of the chemical</b>
	<p>Main properties and lack of information considered:</p> <ul style="list-style-type: none"> <li>- Developmental toxicity: <ul style="list-style-type: none"> <li>rat, oral: NOEL embryo-foetotoxicity: 2 mg/kg bw/d (maternal NOEL: 2 mg/kg bw/d),</li> <li>rat, oral: NOEL embryo-foetotoxicity: 2.5 mg/kg bw/d (maternal NOEL: 2.5 mg/kg bw/d),</li> <li>rabbit, oral: NOEL embryo-foetotoxicity: 0.8 mg/kg bw/d (maternal NOEL: 0.8 mg/kg bw/d),</li> <li>rabbit, oral: NOEL embryotoxicity: 1.25 mg/kg bw/d (maternal NOEL: 1.5 mg/kg bw/d),</li> <li>rat, dermal: NOEL embryo-foetotoxicity: 5 mg/kg bw/d (maternal NOEL: 5 mg/kg bw/d),</li> <li>rat, oral: NOEL embryotoxicity: 3 mg/kg bw/d (maternal NOEL: 3 mg/kg bw/d).</li> </ul> </li> <li>- No AOEL available.</li> <li>- No ADI available.</li> </ul> <p>Full Report on dinoterb (ECCO-Team, 1348/ ECCO/BBA/97 of 14 April 1997).</p>

<b>1.8.3</b>	<b>Description of ecotoxicological properties of the chemical</b>
	<p>Properties and lack of information:</p> <p>a) <u>Fate and behaviour</u>:</p> <ul style="list-style-type: none"> <li>Soil: Degradation not sufficiently documented,</li> <li>Mobility: no acceptable data for field studies,</li> <li>Dinoterb is slowly degraded in water sediment (50 % in 94 days),</li> </ul> <p>b) <u>Ecotoxicity</u></p> <ul style="list-style-type: none"> <li>Serious risks to birds and mammals,</li> <li>High toxicity for fish and <i>Daphnia</i> was concluded,</li> <li>No information was presented for bees and other arthropods,</li> <li>The preliminary data provided indicated a risk to earthworms,</li> <li>From the data available, it was concluded dinoterb is toxic to soil micro organisms.</li> </ul> <p>Full Report on dinoterb (ECCO-Team, 1348/ ECCO/BBA/97 of 14 April 1997).</p>

<b>2. FINAL REGULATORY ACTION</b>	
<b>2.1</b>	The chemical is: <input checked="" type="checkbox"/> banned OR <input type="checkbox"/> severely restricted
<b>2.2</b>	<b>Information specific to the final regulatory action</b>
<b>2.2.1</b>	<p><b>Summary of the final regulatory action</b></p> <p>It is prohibited to place on the market or use plant protection products containing dinoterb. Dinoterb is not included as an active ingredient in Annex I to Directive 91/414/EEC. The authorisations for plant protection products containing dinoterb were withdrawn within a period of 6 months from the Commission Decision 98/269/EC. From the date of decision, no authorisations for plant protection products containing dinoterb will be granted or renewed.</p>
<b>2.2.2</b>	<p><b>Reference to the regulatory document</b></p> <p>Commission Decision 98/269/EC of 7 April 1998 concerning the non-inclusion of dinoterb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Official Journal of the European Communities L117 of 21/04/1998, p. 13) (copy attached).</p>
<b>2.2.3</b>	<p><b>Date of entry into force of the final regulatory action</b></p> <p>6/10/1998 (Authorisations for plant protection products containing dinoterb were withdrawn within a period of 6 months from the date of the final regulatory action).</p>

2.3	Was the final regulatory action based on a risk or hazard evaluation?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<b>If yes, give information on such evaluation</b>			
It was concluded that dinoterb could not fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC.			
The principal issues which laid to these overall conclusions relate mainly to concerns about human health protection under the proposed conditions of use. Additionally, important data gaps made it impossible to further investigate environmental safety.			
<b>Concerns:</b>			
a) Human health protection:			
The data available indicate a high risk or danger to health. The main problem areas are:			
- Teratogenicity: dinoterb is classified as a substance which should be regarded as if it impairs fertility in humans (Toxic; R61: may cause harm to the unborn child).			
- The risk for the operator and the consumers cannot be assessed as no AOEL and no ADI are available.			
b) Environment:			
The data available indicate a high risk or danger to terrestrial and aquatic organisms. The main problem areas are the toxicity to birds, earthworms, soil micro-organisms, fish and <i>Daphnia</i> .			
<b>Reference to the relevant documentation</b>			
Review Report 8083/VI/97-rev 4 of 16 December 1997, copy attached, and supporting background documents (dossier, monograph, and the peer review report under the Peer Review Programme (ECCO April 1997))			
2.4	<b>Reasons for the final regulatory action</b>		
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
<b>If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers</b>			
Based on available data, none of the intended uses are considered acceptable as regards operator exposure to the active substance and consumers exposure to potential residues resulting from use.			
<b>Reference to the relevant documentation</b>			
Review Report 8083/VI/97-rev 4 of 16 December 1997, copy attached, and supporting background documents (dossier, monograph, and the peer review report under the Peer Review Programme (ECCO, April 1997))			
<b>Expected effect of the final regulatory action</b>			
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
<b>If yes, give summary of the known hazards and risks to the environment</b>			
High risk or danger for terrestrial and aquatic organisms.			
<b>Reference to the relevant documentation</b>			
Review Report 8083/VI/97-rev 4 of 16 December 1997, copy attached, and supporting background documents (dossier, monograph, and the peer review report under the Peer Review Programme (ECCO, April 1997))			
<b>Expected effect of the final regulatory action</b>			
Complete risk reduction for plant protection use			
2.5	<b>Category or categories where the final regulatory action has been taken</b>		
2.5.1	Final regulatory action has been taken for the chemical category	<input type="checkbox"/> Industrial	
<b>Use or uses prohibited by the final regulatory action</b>			
Not relevant.			
<b>Use or uses that remain allowed</b>			
Not relevant			

2.5.2	Final regulatory action has been taken for the chemical category	<input checked="" type="checkbox"/> Pesticide
	<b>Formulation(s) and use or uses prohibited by the final regulatory action</b> All applications as plant protection products are prohibited.	
	<b>Formulation(s) and use or uses that remain allowed</b> EU Member States may have granted a period of grace for disposal, storage, placing on the market and use of existing stocks, no longer than 18 months from the date of notification of Commission Decision Commission Decision 98/269/EC of 7 April 1998.	
2.5.3	Estimated quantity of the chemical produced, imported, exported and used, where available.	
	<b>Quantity per year (MT)</b>	<b>Year</b>
<b>Produced</b>	Not available	
<b>Imported</b>	Not available	
<b>Exported</b>	Not available	
<b>Used</b>	Not available	
2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions	
	Health protection in states where the substance is used as a plant protection product, particularly for operators, especially in developing countries. A ban would also protect the general public and 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	



<b>PART III : GOVERNMENT AUTHORITIES</b>
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Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
<b>Institution</b>	European Commission
<b>Address</b>	Rue de la Loi 200 B-1049 Brussels Belgium
<b>Telephone</b>	+32.2.2994860
<b>Telefax</b>	+32.2.2956117
<b>E-mail address</b>	klaus.berend@cec.eu.int
Designated National Authority	
<b>Institution</b>	DG Environment European Commission
<b>Address</b>	Rue de la Loi 200 B-1049 Brussels Belgium
<b>Name of person in charge</b>	Klaus BEREND
<b>Position of person in charge</b>	Administrator
<b>Telephone</b>	+32.2.2994860
<b>Telefax</b>	+32.2.2956117
<b>E-mail address</b>	klaus.berend@cec.eu.int

Date, signature of DNA and official seal: \_\_\_\_\_

*Klaus Berend*

