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**United Nations Environment Programme**

**Food and Agriculture Organization of the United Nations**

**Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade**
**Chemical Review Committee**
Fourth meeting
Geneva, 10–13 March 2008
Item 5 (b) (iii) of the provisional agenda*

**Inclusion of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory action to ban or severely restricted a chemical: carbaryl**

# Carbaryl

## Note by the Secretariat

1. Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade provides that when the Secretariat has received at least one notification from each of two prior informed consent (PIC) regions regarding a particular chemical that it has verified meet the requirements of Annex I to the Convention it shall forward them to the Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III and a decision guidance document drafted.

2. The Secretariat has received notifications relating to carbaryl that meet the information requirements of Annex I from two different PIC regions (Europe (European Community) and Near East (Jordan)) . Summaries of those notifications were included in PIC Circular XVIII of December 2003 and PIC Circular XXVI of December 2007, respectively. The notifications, as received from the notifying countries, are contained in the annex to the present note.

3. Where available, the supporting documentation provided by Jordan and the European Community is set out in documents UNEP/FAO/RC/CRC 9/5/Add.1 and Add.2, respectively.

4. A list of other notifications previously considered by the Chemical Review Committee is set out in document UNEP/FAO/RC/CRC.4/INF/5.

* UNEP/FAO/RC/CRC.4/1

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# Annex

## Notification of final regulatory action for carbaryl by Jordan

## Notification of final regulatory action for carbaryl by European Community

*Interim Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*

UNEP

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

IMPORTANT: See instructions before filling in the form

COUNTRY: JORDAN

## PART I: PROPERTIES, IDENTIFICATION AND USES

| 1. | IDENTITY OF CHEMICAL | |
|---|---|---|
| 1.1 | **Common name** | CARBARYL |
| 1.2 | **Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists** | IUPAC name 1-naphthyl methylcarbamate<br>Chemical Abstracts name 1-naphthalenyl methylcarbamate |
| 1.3 | **Trade names and names of preparations** | Sevin WP -CARBIN WP |
| 1.4 | **Code numbers** | |
| 1.4.1 | **CAS number** | CAS RN *[63-25-2]* EEC no. 200-555-0 |
| 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 | θ This is a first time notification of final regulatory action on this chemical ( YES ) |
| 1.5.2 | θ This is a modification of a previous notification of final regulatory action on this chemical.<br>The sections modified are: _____<br>θ This notification replaces all previously submitted notifications on this chemical. |
| | Date of issue of the previous notification: _____ |

## 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**

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CH

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

| 1.6 Information on hazard classification where the chemical is subject to classification requirements | |
|---|---|
| **International classification systems** | **Hazard class** |
| | Toxicity class WHO (a.i.) II |
| | |
| | |
| | |
| | |
| **Other classification systems** | **Hazard class** |
| | |
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| 1.7 Use or uses of the chemical | |
|---|---|
| 1.7.1 | θ **Pesticide** |
| | **Describe the uses of the chemical as a pesticide in your country:** |
| 1.7.2 | θ **Industrial** |
| | **Describe the industrial uses of the chemical in your country:** |

| 1.8 Properties | |
|---|---|
| 1.8.1 | **Description of physico-chemical properties of the chemical** |
| | **Composition** Tech. grade is ≥99% pure. **Mol. wt.** 201.2 **M.f.** $C_{12}H_{11}NO_2$ **Form** Colourless to light tan crystals. **M.p.** 142 °C **V.p.** $4.1 \times 10^{-2}$ mPa (23.5 °C) $K_{OW}$ logP = 1.85 **Henry** $7.39 \times 10^{-5}$ Pa $m^3$ $mol^{-1}$ (calc.) **S.g./density** 1.232 (20 °C) **Solubility** In water 120 mg/l (20 °C). Readily soluble in polar organic solvents. In dimethylformamide, dimethyl sulfoxide 400-450, acetone 200-300, cyclohexanone 200-250, isopropanol 100, xylene 100 (all in g/kg, 25 °C). **Stability** Stable under neutral and weakly acidic conditions. Hydrolysed in alkaline media to 1-naphthol; $DT_{50}$ c. 12 d (pH 7), 3.2 h (pH 9). Stable to light and heat. **F.p.** |

| 1.8.2 | **Description of toxicological properties of the chemical** |
|---|---|

| | | |
|---|---|---|
| | **Reference to the relevant documentation** | |
| | FAO PLANT PRODUCTION & PROTECTION PAPER 62-1984 | |
| | **Expected effect of the final regulatory action** | |
| | NOTHING | |

| | | |
|---|---|---|
| 2.4.2 | **Is the reason for the final regulatory action relevant to the environment?** | θ **No** |
| | **If yes, give summary of the known hazards and risks to the environment** | |
| | **Reference to the relevant documentation** | |
| | **Expected effect of the final regulatory action** | |

| | | |
|---|---|---|
| 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** | θ **Industrial** |
| | **Use or uses prohibited by the final regulatory action** | |
| | ALL FORMULATION.AND ALL USES FOR PLANT PROTETION | |
| | **Use or uses that remain allowed** | |

| | |
|---|---|
| | |

| | |
|---|---|
| | ARC ref. 12 class 3 Oral Acute oral $LD_{50}$ for rats 264, female rats 500, rabbits 710 mg/kg. Skin and eye Acute percutaneous $LD_{50}$ for rats >4000, rabbits >2000 mg/kg. Slight eye irritant, mild skin irritant (rabbits). Inhalation $LC_{50}$ (4 h) for rats 3.28 mg/l air. NOEL (2 y) for rats 200 mg/kg diet. ADI (JMPR) 0.003 mg/kg b.w. [2000]. |
| 1.8.3 | **Description of ecotoxicological properties of the chemical** |
| | ng pheasants >2000, Japanese quail 2230, pigeons 1000-3000 mg/kg. **Fish** $LC_{50}$ (96 h) for rainbow trout 1.3, sheepshead minnow 2.2, bluegill sunfish 10 mg/l. **Daphnia** $LC_{50}$ (48 h) 0.006 mg/l. **Algae** $EC_{50}$ (5 d) for *Selenastrum capricornutum* 1.1 mg/l. **Other aquatic spp.** $LC_{50}$ (96 h) for mysid shrimp (*Mysidopsis bahia*) 0.0057 mg/l; $LC_{50}$ (48 h) for Eastern oyster (*Crassostrea virginica*) 2.7 mg/l. **Bees** Toxic to bees; $LD_{50}$ (topical) 1 µg/bee. **Worms** $LC_{50}$ (28 d ) 106-176 mg/kg soil. **Other beneficial spp.** Toxic to beneficial insects |

## PART II: FINAL REGULATORY ACTION

| | | |
|---|---|---|
| 2. | **FINAL REGULATORY ACTION** | |
| 2.1 | **The chemical is:** θ **banned** | |
| 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 carbaryl | |
| 2.2.2 | **Reference to the regulatory document** | |
| | SESSION .300 DATE 16/2/1993 | |
| 2.2.3 | **Date of entry into force of the final regulatory action** | |
| | 1993 1.5.1993 | |

| | | |
|---|---|---|
| 2.3 | **Was the final regulatory action based on a risk or hazard evaluation?** | θ Yes |
| | **If yes, give information on such evaluation** | |
| | **Reference to the relevant documentation** | |
| | FAO PLANT PRODUCTION & PROTECTION PAPER 62-1984 | |

| | | |
|---|---|---|
| 2.4 | **Reasons for the final regulatory action** | |
| 2.4.1 | **Is the reason for the final regulatory action relevant to the human health?** | θ Yes |
| | **If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers** | |
| | **It can cause human male reproductive disorder ( decrease fertility and sterility )**<br>**Risk of potential carcinogenicity** | |

| 2.5.2 | Final regulatory action has been taken for the chemical category | θ Pesticide |
|---|---|---|
| | **Formulation(s) and use or uses prohibited by the final regulatory action** | |
| | ALL FORMULATION | |
| | **Formulation(s) and use or uses that remain allowed** | |
| | | |

| 2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available. | | |
|---|---|---|
| | **Quantity per year ( KG )** | **Year** |
| **Produced** | 1376KG | 92 |
| **Imported** | 5400 KG | 92 |
| **Exported** | - | |
| **Used** | 18776 KG | 92 |

| 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** | |
|---|---|---|
| | DIMETHOATE -CYPERMETHRIN LESS RISK THAN CARBARYL | |
| 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 AGRICULTURE |
| **Designated National Authority** | |
| **Address** | P.O.BOX :961044- -2099 AMMAN |
| **Name of person in charge** | MAHMOUD AL-KHTOOM |
| **Position of person in charge** | DIRECTOR OF PLANT PROTECTION DEPARTMENT |
| **Telephone** | 5686151 |
| **Telefax** | 5686310 |
| **E-mail address** | PRD@JOINNET.COM.JO |

**Date, signature of DNA and official seal:** _____ Mohammad R. Katbeh Bad

وزارة الزراعة
قسم المبيدات

*Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*

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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom)

## PART I: PROPERTIES, IDENTIFICATION AND USES

| 1. | **IDENTITY OF CHEMICAL** | |
|---|---|---|
| 1.1 | **Common name** | carbaryl |
| 1.2 | **Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists** | IUPAC: 1-naphthyl-N-methylcarbamate<br><br>CA: 1-naphthalenyl-methylcarbamate |
| 1.3 | **Trade names and names of preparations** | Formulation types: Suspension concentrate<br>Trade names include: Sevin XLR plus, Tercyl |
| 1.4 | **Code numbers** | |
| 1.4.1 | **CAS number** | 63-25-2 |
| 1.4.2 | **Harmonized System customs code** | 2924 29 95 |
| 1.4.3 | **Other numbers (specify the numbering system)** | EINECS: 200-555-0<br>CIPAC: 26 |

| 1.5 | **Indication regarding previous notification on this chemical, if any** |
|---|---|
| 1.5.1 | X This is a first time notification of final regulatory action on this chemical. |
| 1.5.2 | θ This is a modification of a previous notification of final regulatory action on this chemical.<br>The sections modified are: _____<br>θ This notification replaces all previously submitted notifications on this chemical. |

## PLEASE RETURN THE COMPLETED FORM TO:


**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**

**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: _____ |

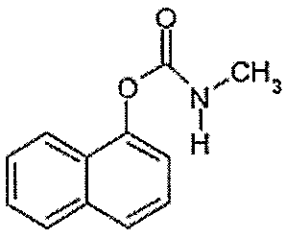
| 1.6 Information on hazard classification where the chemical is subject to classification requirements | |
|---|---|
| **International classification systems** | **Hazard class** |
| WHO Classification | Acute Hazard. II Moderately hazardous |
| EPA | Acute rating. Product label 2 Moderately toxic<br>(Formulation) I<br>('Tercyl' 85WP) II<br>('Sevin' 80S) III |
| IARC | 3, Unclassifiable |
| UN | - |
| Classification of the EC in accordance with Council directive 67/548/EEC | Xn; Harmful<br>N; Dangerous for the environment<br>Carcinogen Category 3<br>R20; Harmful by inhalation<br>R22; Harmful if swallowed<br>R40; Limited evidence of a carcinogenic effect<br>R50; Very toxic to aquatic organisms |
| **Other classification systems** | **Hazard class** |
| | |

| 1.7 Use or uses of the chemical | |
|---|---|
| 1.7.1 | X **Pesticide** |
| | **Describe the uses of the chemical as a pesticide in your country:** |
| | Carbaryl belongs to a class of carbamate insecticides and acaricides. It is a weak cholinesterase inhibitor. Carbaryl is used as a plant growth regulator, applied by tractor mounted orchard sprayer to apple trees at a rate of 0.9 kg/ha for the purpose of fruit thinning. |
| 1.7.2 | θ **Industrial** |
| | **Describe the industrial uses of the chemical in your country:** |
| | |

## 1.8 Properties

### 1.8.1 Description of physico-chemical properties of the chemical

**Minimum Purity:** 990 g/kg
**FAO Specification:** 980 ± 20 g/kg
**Molecular Formula:** $C_{12}H_{11}NO_2$
**Molecular Mass:** 201.2 g/mol
**Structural Formula:**



**Appearance:** White powder (purity 99.1%)
**Odour:** No characteristic odour
**Melting Point:** 138.0 ± 0.2°C (purity 99.1%)
**Boiling Point:** 210°C (Mean boiling point by differential Scanning Calorimetry)
212.0 ± 0.2°C (boiling point by photocell detection method) (purity 99.1%)
**Vapour Pressure:** $4.16 \times 10^{-5} \pm 4.51 \times 10^{-6}$ Pa at 23.5°C (purity 99.1%)
**Volatility:**
**Henry's Law Constant:** $9.2 \times 10^{-5}$ Pa $m^3$ $mol^{-1}$ at 20°C
**Solubility in Water:** at 20 ± 0.5°C (purity 99.1%) (mg/l)
pH 4: 9.4 ± 0.2
pH 7: 9.1 ± 0.3
pH9: 7.2 ± 0.3

**Solubility in Organic Solvents:** at 20°C ± 0.5 (purity 99.1%) (g/l):

| | |
|---|---|
| methanol | 75-100 |
| acetone | 150-200 |
| ethyl acetate | 75-100 |
| 1,2 dichloroethane | 100-200 |
| xylene: | 9.86 |
| n-heptane | 0.25 |
| acetonitrile | 100-200 |
| dimethylsulfoxide | >600 |

**Density:** 1.21 ± 0.01 g/$cm^3$ at 20°C
**Dissociation Constant (pKa):** 10.4 ± 0.4 at 24.3 ± 0.1°C (purity 99.7%)
**Log $P_{ow}$:** 2.36 ± 0.012 at 23 ± 2°C in Milli-Q purified water (neutral pH) (purity 99.8%)
**Hydrolysis Rate:** pH5: stable
pH7: 11.6-12.5 days
pH9: 3.2 hours

Carbaryl is **not a readily combustible solid** and is **not explosive**

| | |
|---|---|
| 1.8.2 | **Description of toxicological properties of the chemical** |

**Absorption, distribution, excretion and metabolism in mammals:**
Carbaryl is rapidly absorbed and is widely distributed in rats, with the highest levels reported in the kidneys after seven days. Carbaryl does not appear to accumulate and is extensively metabolized; only 2.9% of an administered dose was detected unchanged in the urine. The major metabolic pathways were reported to be arene oxide formation and conjugation with glutathione, carbamate hydrolysis to 1-naphthol and oxidation of the N-methyl moiety.

**Acute Toxicity:**

| | |
|---|---|
| $LD_{50}$ (Sprague-Dawley rat, oral) | 614 mg/kg bw |
| $LD_{50}$ (Sprague Dawley rat, dermal) | >5000 mg/kg bw |
| $LD_{50}$ (Female Sprague Dawley rat, inhalation (nose only), 4 hour) | 2.43 mg/l air |

**Irritation & Sensitisation:**
Carbaryl was reported to be non-irritating to the skin and eyes of rabbits. Carbaryl did not induce hypersensitivity in guinea pigs in the Magnusson and Klingman test.

**Short term Toxicity:**
Carbaryl was assessed in studies in rats, mice and dogs. The critical effect was the inhibition of cholinesterase activity while the target organ was the liver (weight increase and histopathology changes).

Rat (dermal, four weeks): NOAEL = 20 mg/kg bw/day, LOAEL = 100 mg/kg bw/day (inhibition of brain cholinesterase activity).
NOAEL of 20 mg/kg bw/day was considered the relevant dermal NOAEL

Male dog (oral, one year): NOAEL = 3.37 mg/kg bw/day, LOAEL = 11.23 mg/kg bw/day
Female dog (oral, one year): NOAEL = <3.73 mg/kg bw/day, LOAEL = 3.73 mg/kg bw/day
(inhibition of brain and red blood cell cholinesterase activity, decreased bodyweight and food consumption).
NOAEL of lower than 3.37 mg/kg bw/day in this study was considered the relevant oral NOAEL

**Genotoxicity:**
Negative results have been reported in *in vitro* Ames tests in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation. Negative results were reported in *in vitro* Chinese hamster ovary cell gene mutation assays without metabolic activation. An equivocal result was obtained in one study with metabolic activation; however, subsequent assays with a new batch of S9 did not confirm this result. Negative results were reported in an *in vitro* Chinese hamster ovary chromosome aberration assay without metabolic activation. Positive results were obtained in the presence of S9. Negative results were reported in an unscheduled DNA synthesis assay in rat hepatocytes.

Negative results have been reported in an *in vivo* micronucleus test and a DNA and protein binding assay conducted in mice and a chromosome aberration assay conducted in rats.

In conclusion, the weight of evidence indicates that carbaryl is not an *in vivo* genotoxic agent.

**Long term toxicity and Carcinogenicity:**

Rat (oral, two years): NOAEL = 10 mg/kg bw/day, LOAEL = 60.2 mg/kg bw/day (inhibition of erythrocyte and brain cholinesterase activity).
NOAEL of 10 mg/kg bw/day was considered the relevant chronic NOAEL.

Mice (oral, two years): NOAEL = 14.7 mg/kg bw/day, LOAEL = 146 mg/kg bw/day (inhibition of erythrocyte and brain cholinesterase activity and histopathological changes of the bladder).

In a two-year study, rats were administered carbaryl in the diet at doses corresponding to 0, 10, 60.2 and 349.5 and 0, 12.6, 78.6 and 484.6 mg/kg bw/day in male and female rats, respectively. At the top dose (a concentration exceeding the Maximum Tolerated Dose), an increased incidence of urinary and bladder papillomas, carcinomas and transitional cell hyperplasia, kidney carcinomas, liver adenomas and hepatocellular hypertrophy and thyroid adenomas and carcinomas and follicular cell hypertrophy were noted in both sexes at the top dose. An increase in transitional cell hyperplasia of the kidney was also noted in males at the top dose.

In a two-year study, mice were administered carbaryl in the diet at doses corresponding to 0, 15, 146 and 1248 and 0, 18, 181 and 1441 mg/kg bw/day in male and female mice, respectively. At the top dose, an increased incidence of renal tubular cell adenomas and carcinomas were observed in males and an increased incidence of hepatocellular adenomas and carcinomas were observed in females. At the low-dose, an increased incidence of haemangiomas and haemangiosarcomas were observed in male mice.
The relevant NOAEL for non-neoplastic lesions was 15 mg/kg bw/day while neoplastic tumours were seen at 1248 mg/kg bw/day. Therefore a NOAEL for carcinogenicity was not established.

Mechanistic studies suggested that the tumourigenic response was due to cell proliferation associated with a mitogenic effect of carbaryl or one of its metabolites. The results identified carbaryl as a weak barbiturate-type inducer of cytochrome P450 in the mouse liver.

**Reproductive Toxicity:**
Rat (Two-generation reproduction study):
Parental NOAEL = 4.67 mg/kg bw/day (decreased bodyweight and food consumption)
Reproductive NOAEL = 4.67 mg/kg bw/day (reduction in number of F2 pups, litter and F2 pup survival).
It was concluded that carbaryl had no effect on sperm morphology.

Rat (Teratology study)
Maternal NOAEL = 4 mg/kg bw/day (decreased bodyweight).
Developmental NOAEL = 4 mg/kg bw/day (decreased foetal bodyweight).

Rabbit (Teratology study)
Maternal NOAEL = 5 mg/kg bw/day (inhibition of red blood cell cholinesterase).
Developmental NOAEL = 50 mg/kg bw/day (decreased foetal bodyweight, decreased litter size).

**Endocrine disruption**
-

**Neurotoxicity:**
Rat (oral gavage, single dose, no control group): NOAEL = 10 mg/kg bw/day, LOAEL = 50 mg/kg bw/day (tremors, autonomic signs and decreased bodyweight) (3).
Rat (oral gavage, single dose): LOAEL = 10 mg/kg bw/day (lowest dose tested) (inhibition of brain and erythrocyte cholinesterase activity) (3).
Rat (oral gavage, single dose): LOAEL = 10 mg/kg bw/day (lowest dose tested) (inhibition of brain and erythrocyte cholinesterase activity) (3).
Rat (oral gavage, single dose): NOAEL = 10 mg/kg bw/day (functional observed battery changes, reduced motor activity, decreased bodyweight) (3).
Rat (oral gavage, thirteen weeks): NOAEL = 1 mg/kg bw/day (inhibition of cholinesterase activity, functional observed battery changes, decreased bodyweight and food consumption). No signs of developmental neurotoxicity were recorded. This study was used to derive the ARfD.

**Safety Values:**
EU Risk Assessment Acceptable Daily Intake (ADI) = 0.0075 mg/kg bw/day (based on the LOAEL of 14.73 mg/kg bw/day (rounded to 15 mg/kg bw/day) from a two-year mice carcinogenicity study and an uncertainty factor of 2000 to account for inter- and intra-species variation, the severity of effects and the use of a LOAEL).

Acceptable Operator Exposure Level (AOEL) = 0.01 mg/kg bw/day (based on the NOAEL of 1 mg/kg bw/day from a thirteen-week rat neurotoxicity study and an uncertainty factor of 100 to account for inter- and intra-species variation).

EU Risk Assessment Acute Reference Dose (ARfD) = 0.01 mg/kg bw/day (based on the NOAEL of 1 mg/kg bw/day from a thirteen-week rat neurotoxicity study and an uncertainty factor of 100 to account for inter- and intra-species variation).

**1.8.3 Description of ecotoxicological properties of the chemical**

**Soil**
In an experiment conducted in sandy-loam soil, 94% of an applied radioactive dose of 11.2 mg/kg soil was reported to be degraded after 14 days, with 59.7% of the total applied radioactivity recovered as carbon dioxide. A half-life of 4.0 days was calculated. In another aerobic study, conducted using five different soils, mineralisation to carbon dioxide accounted for 15-58% of an applied concentration of radioactive carbaryl after 100 days. The most significant extractable breakdown product detected in soil was reported to be 1-naphthol, which accounted for 35% of the applied radioactivity in sandy-loam soil after 1 day. This decreased to 2.8% of the applied radioactivity after 2 days. Under anaerobic conditions, the degradation pattern was similar, although 1-naphthol was detectable for a longer period. From absorption studies, the calculated $K_foc$ values ranged from 177 to 249 mL/g (mean 211 mL/g) indicating that carbaryl is moderately mobile in soil. There is no evidence of a correlation of adsorption with pH.

**Water**
Carbaryl is moderately soluble (9.1 ± 0.3 mg/l at 20 ± 0.5°C, pH 7). Carbaryl is reported to be more susceptible to hydrolysis under basic conditions than acidic conditions. Carbaryl appears to be less susceptible to hydrolysis in non-sterile conditions ($DT_{50}$ of 12 days at 25°C, pH 7). Carbaryl has a reported vapour pressure of $4.16 \times 10^{-5}$ Pa, indicating slight volatilisation from water surfaces may occur. Photolysis is not expected to be a significant route of degradation. In water sediment studies, carbaryl was non-persistent in both the water and sediment phase (water phase $DT_{50}$ of 1.2-5 days and whole system $DT_{50}$ of 1.62-9.9 days). Carbaryl is reported to be readily biodegradable according to OECD 301D readily biodegradability test.

**Air**
Calculations using the Atkinson method for indirect photooxidation in the atmosphere estimate a half-life for carbaryl of 0.377 days.

**Ecotoxicology**

• Terrestrial birds

| | |
|---|---|
| Mallard duck (*Anas platyrhynchos*) (oral) | $LD_{50}$ = >2000 mg/kg bw |
| Mallard duck (*Anas platyrhynchos*) (oral) | $LD_{50}$ = >2564 mg/kg bw |
| Mallard duck (*Anas platyrhynchos*) (diet) | NOEC = 300 mg/kg diet (30 mg/kg bw/day) |
| Japanese Quail (*Coturnix japonica*) (oral) | $LD_{50}$ = 2290 mg/kg bw |
| Japanese Quail (*Coturnix japonica*) (diet) | $LC_{50}$ = >5000 mg/kg diet (>1000 mg/kg bw/day) |
| Ring-necked pheasant (*Phasianus colchicus*) (oral) | $LD_{50}$ = >2000 mg/kg bw |

• Honey bee

| | | |
|---|---|---|
| Acute oral toxicity | 72 hour | $LD_{50}$ = ≥0.21 µg/bee (technical) |
| Acute oral toxicity | 72 hour | $LD_{50}$ = 1.08 µg/bee (formulation) |
| Acute dermal toxicity | 72 hour | $LD_{50}$ = 0.14 µg/bee (technical) |
| Acute dermal toxicity | 72 hour | $LD_{50}$ = >3.84 µg/bee (formulation) |

• Earthworm

| | |
|---|---|
| Earthworm (*Eisenia foetida*) (14 day) | $LC_{50}$ = 151 mg/kg |
| Earthworm (*Eisenia foetida*) (14 day) | NOEC = <50 mg/kg |
| Earthworm (*Eisenia foetida*) (14 day) | $LC_{50}$ = 654 mg/kg |
| Earthworm (*Eisenia foetida*) (28 day) | $LC_{50}$ = 174 mg/kg |
| Earthworm (*A. caliginosa*) (14 day) | $LC_{50}$ = <4 mg/kg |

• Arthropod

| | |
|---|---|
| Aphid parasitoid (*Aphidius rhopalosiphi*) | $LR_{50}$ (mortality) = 0.0247 g/ha (Sevin XLR Plus) |
| Mite (*Typhlodromus pyri*) | $LR_{50}$ (mortality) = 457 g/ha (Sevin XLR Plus) |
| Spider (*Pardosa sp.*) | $LR_{50}$ (mortality) = >28.9 g/ha (Sevin XLR Plus) |
| Green lacewing (*Chrysoperla carnea*) | $LR_{50}$ (mortality) = <1.1 g/ha (Sevin XLR Plus). |

• Freshwater species

| | | |
|---|---|---|
| Duckweed (*Lemna gibba*) | 7 day | $IC_{50}$ (frond number) = 13.7 mg/l |
| Duckweed (*Lemna gibba*) | 7 day | NOEC (renewal) = 5.0 mg/l |
| Waterflea (*Daphnia longispina*) | 48 hour | $EC_{50}$ (effect not stated) = 0.0078 mg/l |
| Waterflea (*Daphnia magna*) | 48 hour | NOEC (effect not stated) = 0.0033 mg/l |
| Waterflea (*Daphnia pulex*) | 48 hour | $EC_{50}$ (effect not stated) = 0.0064 mg/l |
| Rainbow trout (*Oncorynchus mykiss*) | 96 hour | $LD_{50}$ (mortality) = 0.61 mg/l (Sevin) |
| Fathead minnow (*Pimephales promelas*) | 34 day | NOEC (effect not stated) = 0.21 mg/l (Sevin) |

• Saltwater species

| | | |
|---|---|---|
| Algae (*Skeletonema sp.*) | 120 hour | $EC_{50}$ (biomass) = 0.70 mg/l |
| Algae (*Skeletonema sp.*) | 120 hour | NOEC = 0.36 mg/l |
| Sheepshead minnow (*Cyprinodon variegates*) | 96 hour | $LD_{50}$ (mortality) = 2.60 mg/l |

## 1.9 References used in Part I

EFSA (2006). Conclusion Regarding the Peer Review of the Pesticide Risk of the Active Substance Carbaryl. Finalised 12th May 2006. EFSA Scientific Report 80, 1-71

EU (2006). Final Addendum to the Draft Assessment Report (DAR). Initial Risk Assessment Provided by the Rapporteur Member State Spain for the Existing Active Substance Carbaryl of the Second Stage of the Review Programme Referred to in Article 8(2) of Council Directive 91/414/EEC. Part 1.

EU (2006). Final Addendum to the Draft Assessment Report (DAR). Initial Risk Assessment Provided by the Rapporteur Member State Spain for the Existing Active Substance Carbaryl of the Second Stage of the Review Programme Referred to in Article 8(2) of Council Directive 91/414/EEC. Part 2.

Monograph Volume III (2004). Chapter 1 Annex B Carbaryl. B-1: Identity

Monograph Volume III (2004). Chapter 6 Annex B Carbaryl. B-6: Toxicology and Metabolism

# PART II: FINAL REGULATORY ACTION

| | | | | |
|---|---|---|---|---|
| **2.** | **FINAL REGULATORY ACTION** | | | |
| **2.1** | **The chemical is:** | X **banned** | **OR** | θ **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 carbaryl. Carbaryl is not included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC. The authorizations for plant protection products containing carbaryl had to be withdrawn by 21 November 2007. From 25 May 2007, no authorizations for plant protection products containing carbaryl can be granted or renewed. | | | |
| **2.2.2** | **Reference to the regulatory document** | | | |
| | Commission Decision (EC) 2007/355/EC of 21 May 2007 concerning the non-inclusion of carbaryl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (Official Journal of the European Union L 133 of 25.05.2007, p. 40-41) (copy attached and also available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_133/l_13320070525en00400041.pdf ) | | | |
| **2.2.3** | **Date of entry into force of the final regulatory action** | | | |
| | 25 May 2007. Any period of grace granted by the Member States under Article 4(6) of Directive 91/414/EEC shall be as short as possible and shall expire not later than 21 November 2008. | | | |

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| **2.3** | **Was the final regulatory action based on a risk or hazard evaluation?** | X **Yes** | θ **No** |
| | **If yes, give information on such evaluation** | | |
| | Directive 91/414/EEC provides for the European Commission to carry out a programme of work for the examination of existing active substances used in plant protection products which were already on the market on 25 July 1993, with a view to their possible inclusion in Annex I to the Directive.<br><br>Within this context, a company notified its wish to secure the inclusion of carbaryl as an authorised active ingredient. A Member State (Spain) was designated to undertake a risk assessment based on the dossier submitted by the notifier (Aventis CropScience before merging with Bayer CropScience). The assessment report was subject to peer review by the Member States and the European Food Safety Authority (EFSA), during which the Commission undertook extensive consultations with experts of the Member States as well as with the notifier.<br><br>In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, the EFSA organised the consultation on the draft assessment report by all the Member States. The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review). The results were then reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH).<br><br>It was concluded that carbaryl was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to consumers' exposure and carcinogenicity as well as a high long-term risk for insectivorous birds and a high acute risk to herbivorous mammals, a high acute and long-term risk to aquatic organisms and a high risk for beneficial arthropods. | | |

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| | **Reference to the relevant documentation** |
| | Review Report for the active substance carbaryl (SANCO/10049/2006 final) and supporting background documents (e.g. dossier, monograph and the EFSA peer review report under the Peer Review Programme) (copy attached and also available at:<br>http://ec.europa.eu/food/plant/protection/evaluation/existactive/list-carbaryl_en.pdf)<br><br>EFSA (2006). Conclusion Regarding the Peer Review of the Pesticide Risk Assessment of the Active Substance Carbaryl. Finalised 12th May 2006. EFSA Scientific Report 80, 1-71. (copy attached and also available at:<br>http://www.efsa.europa.eu/EFSA/PRAPER_Conclusion/praper_concl_sr80_carbaryl_rev1_en,0.pdf) |

| | | |
|---|---|---|
| **2.4** | **Reasons for the final regulatory action** | |
| **2.4.1** | **Is the reason for the final regulatory action relevant to the human health?** | X **Yes** θ **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** | |
| | A robust risk assessment for the safety of the consumer was not possible due to the lack of information on the actual levels of the 4- and 5-hydroxy carbaryl in apples. Considering that the exposure to the parent compound only is close to 50% of the ARfD for some specific population sub-groups, it cannot be excluded that the contribution of the metabolites leads to a global exceedance of the ARfD for those sub-groups.<br>There are also concerns about the carcinogenicity of carbaryl. | |
| | **Reference to the relevant documentation** | |
| | Review Report for the active substance carbaryl (SANCO/10049/2006 final) and supporting background documents (e.g. dossier, monograph and the EFSA peer review report under the Peer Review Programme) (copy attached and also available at:<br>http://ec.europa.eu/food/plant/protection/evaluation/existactive/list-carbaryl_en.pdf)<br><br>EFSA (2006). Conclusion Regarding the Peer Review of the Pesticide Risk Assessment of the Active Substance Carbaryl. Finalised 12th May 2006. EFSA Scientific Report 80, 1-71. (copy attached and also available at:<br>http://www.efsa.europa.eu/EFSA/PRAPER_Conclusion/praper_concl_sr80_carbaryl_rev1_en,0.pdf) | |
| | **Expected effect of the final regulatory action** | |
| | Reduction of risk from the use of plant protection products. | |

| | | |
|---|---|---|
| **2.4.2** | **Is the reason for the final regulatory action relevant to the environment?** | X **Yes** θ **No** |
| | **If yes, give summary of the known hazards and risks to the environment** | |
| | • A high long-term risk to insectivorous birds and a high acute risk to herbivorous mammals.<br>• A high acute and chronic risk to aquatic invertebrates which requires considerable risk mitigation measures (with a 50 m buffer zone, the risk is still not acceptable).<br>• A high risk to non-target arthropods (particularly insects) which requires considerable risk mitigation measures, e.g. no-spray buffer zones of more than 250 m would be required to protect non-target arthropods in the off-field area. | |

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| | **Reference to the relevant documentation** |
| | Review Report for the active substance carbaryl (SANCO/10049/2006 final) and supporting background documents (e.g. dossier, monograph and the EFSA peer review report under the Peer Review Programme) (copy attached and also available at:<br>http://ec.europa.eu/food/plant/protection/evaluation/existactive/list-carbaryl_en.pdf)<br><br>EFSA (2006). Conclusion Regarding the Peer Review of the Pesticide Risk Assessment of the Active Substance Carbaryl. Finalised 12th May 2006. EFSA Scientific Report 80, 1-71. (copy attached and also available at:<br>http://www.efsa.europa.eu/EFSA/PRAPER_Conclusion/praper_concl_sr80_carbaryl_rev1_en,0.pdf) |
| | **Expected effect of the final regulatory action** |
| | Reduction of risk from the use of plant protection products |

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|---|---|---|
| **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** | θ **Industrial** |
| | **Use or uses prohibited by the final regulatory action** | |
| | Not relevant | |
| | **Use or uses that remain allowed** | |
| | Not relevant | |

| | | |
|---|---|---|
| **2.5.2** | **Final regulatory action has been taken for the chemical category** | X **Pesticide** |
| | **Formulation(s) and use or uses prohibited by the final regulatory action** | |
| | All applications as plant protection products | |
| | **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** | | |
| **Imported** | | |
| **Exported** | | |
| **Used** | | |

| | |
|---|---|
| **2.6** | **Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions** |
| | Similar health and environmental problems are likely to be encountered in other countries where the substance is used, particularly in developing countries. |

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| **2.7** | **Other relevant information that may cover:** |
| **2.7.1** | **Assessment of socio-economic effects of the final regulatory action** |
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|---|---|
| **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** | B-1049 Brussels<br>Belgium |
| **Telephone** | +322 296 4135 |
| **Telefax** | +322 296 7617 |
| **E-mail address** | Paul.Speight@ec.europa.eu |
| **Designated National Authority** | |
| **Institution** | DG Environment<br>European Commission |
| **Address** | B-1049 Brussels<br>Belgium |
| **Name of person in charge** | Paul Speight |
| **Position of person in charge** | Deputy Head of Unit |
| **Telephone** | +322 296 4135 |
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**Date, signature of DNA and official seal:** 23/11/07 Paul Speight