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

Country:

European Union Member States are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Carbofuran**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate CA: 2,3-dihydro-2,2-dimethyl-7-benzofuranylmethylcarbamate
1.3	**Trade names and names of preparations**	Furadan 5G, a granule. Diafuran 5G, a microgranule.

1.4 Code numbers

1.4.1	CAS number	1563-66-2
1.4.2	Harmonized System customs code	2932 99

1.4.3	Other numbers (specify the numbering system)	EINECS: 216-353-0 CIPAC: 276 Combined Nomenclature (CN) code of the European Union: 2932 99 00

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.

Date of issue of the previous notification: _____

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☒ banned OR ☐ 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 carbofuran. Carbofuran is not included in the list of approved active ingredients under Regulation (EC) No 1107/2009, which replaces Directive 91/414/EEC. The authorizations for plant protection products containing carbofuran had to be withdrawn by 13 December 2007. As of 16 June 2007, no authorisations for plant protection products containing carbofuran could be granted or renewed.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Commission Decision 2007/416/EC of 13 June 2007 concerning the non-inclusion of carbofuran in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing this active substance (Official Journal of the European Union L 156 of 16.06.2007, p. 30-31) (copy attached and also available at:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_156/l_15620070616en00300031.pdf)

2.2.3 Date of entry into force of the final regulatory action

Complete entry into force of all provisions of Commission Decision 2007/416/EC of 13 June 2007 was 13 December 2008 since all uses of plant protection products containing carbofuran were prohibited as from that date at the latest.

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Carbofuran containing plant protection products are used as acaricides, insecticides and nematicides. However, only its use as an insecticide was considered during the EU review. Insecticide uses involve drilling into soil at sites where maize, sugar beet and sunflowers are grown. Various products were registered for use in some Member States of the EU. Carbofuran is a systemic insecticide with contact and stomach action and functions by inhibiting acetylcholine esterase (AChE). Uses as acaricides and nematicides include crops, such as maize, sugar beet, ornamentals, potato, carrots, brassica, onion, celery, chicory, beetroot, fodder beet, leek, sweetcorn, tournesol, soya, tobacco, rice, garlic, cauliflower, cabbage, tomato, peppers, aubergine, peanuts, melon, water melon, cotton, banana, sorghum and oilseeds. Pests controlled include numerous species of sucking insects, soil insects, chewing insects, nematods, aphids and wireworms.

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

Use or uses that remain allowed (only in case of a severe restriction)

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

All uses as plant protection products

Formulation(s) and use or uses that remain allowed
(only in case of a severe restriction)

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

A risk assessment was carried out on the basis of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009), which provides for the European Commission to issue a work programme for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Article 8(7) of Regulation (EC) No 451/2000.

A Member State was designated to undertake the risk assessment based on the information submitted by the notifiers and to establish a draft assessment report, which was subject to peer review organised by the European Food Safety Authority (EFSA). The conclusions provided by EFSA were reviewed by the Member States and the Commission and submitted to the Standing Committee on the Food Chain and Animal Health (SCFCAH).

The evaluation was based on a review of scientific data taking into account the conditions prevailing in the European Union (intended uses, recommended application rates, good agricultural practices). Only data that has been generated according to scientifically recognised methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognised scientific principles and procedures.

The risk assessment described above resulted in several documents, including:

Review Report for the active substance carbofuran finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 24 November 2006 (SANCO/10054/2006 final)

http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.ViewReview&id=128

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report (2006) 90, p. 1-88.

http://www.efsa.europa.eu/en/efsajournal/doc/90r.pdf

After adoption of the regulatory action banning the use of carbofuran in 2007, the notifier submitted a revised dossier, including additional data, which have been fully peer reviewed and resulted in revised conclusions by EFSA. The notifier withdrew its application after the delivery of the EFSA conclusion. As a consequence, no formal additional regulatory act has been adopted by the European Commission.

EFSA (2009): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report (2009) 310, p. 1-132.

http://www.efsa.europa.eu/en/efsajournal/doc/310r.pdf

It should be noted that this notification also reflects the data originating from the review finalised in 2009 although the regulatory action was based on the review finalised in 2006.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

It was concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The consumer risk assessment, which raised a concern about the acute exposure of vulnerable groups of consumers, in particular children, could not be finalised due to the lack of information as regards certain relevant residues (EFSA, 2006).

The consumer risk assessment mentioned above has been superseded by an updated risk assessment based on new data. The sum of intakes of carbofuran and 3-hydroxy carbofuran from crops was compared with the toxicological reference values for carbofuran. An exceedance of the ADI was noted for toddlers in two models. The acute consumer risk assessment indicates that the ARfD is significantly exceeded for a number of crops consumed by children and by adults/the general population (EFSA, 2009).

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

It was concluded that carbofuran was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC (replaced by Regulation (EC) 1107/2009). The environmental risk assessment

identified a number of concerns with regard to ecotoxicology. The risk for ground water contamination was assessed to be high, but could not be concluded, in particular because the data did not provide sufficient information about a number of metabolites which have a hazardous profile. Furthermore, concerns remain as regards the risk assessment for birds and mammals, aquatic organisms, bees, non target arthropods, earthworms, and soil non-target organisms.

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products containing carbofuran.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced		
imported		
exported		
used		

2.5.2 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.

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**
UN	Acute hazard 1b Highly hazardous

Other classification systems **e.g. EU, USEPA**	**Hazard class**
Classification of the EU in accordance with Council Directive 67/548/EEC	T+ - Very toxic. R26 - Very toxic by inhalation. R28 - Very toxic if swallowed. N - Dangerous for the environment. R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Classification of the EU according to Regulation (EC) No 1272/2008, which implements the UN GHS in the European Union	Acute Tox. 2 * - H330 - Fatal if inhaled. Acute Tox. 2 * - H300 - Fatal if swallowed. Aquatic Acute 1 - H400 - Very toxic to aquatic life. Aquatic Chronic 1 - H410 - Very toxic to aquatic life with long lasting effects. (* = This classification shall be considered as a minimum classification.)
US EPA	Product Label Highly toxic

3.2 Further information on the properties of the chemical

It should be noted that this notification also reflects the data originating from the review finalised in 2009 although the regulatory action was based on the review finalised in 2006.

3.2.1 Description of physico-chemical properties of the chemical

Minimum Purity: 960 g/kg for the technical material of Arysta

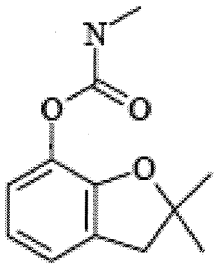
980 g/kg for the technical material of FMC

FAO Specification: Not available

Molecular Formula:C12H15NO3

Molecular Mass: 221.3 g/mol

Structural Formula:



Appearance:
Arysta = white crystalline soil (purified active substance)
FMC = off-white powder (99.3%)

Odour:
Arysta = odourless (purified active substance)
FMC = aromatic acid-like odour (99.3%)

Melting Point:
Arysta = 153.1°C (98.2%)
FMC = 151.2-153.7°C (99.3%)

Boiling Point:
Arysta = 276°C (98.2%) (partial decomposition)
FMC = 254.1°C (99.6%) (no decomposition)

Surface Tension:
Arysta = 48.9 mN/m at 20.3°C (90% saturated solution)
FMC = 54.7 mN/m at 20°C (90% saturated solution)

Vapour Pressure:
Arysta = 2.25 $x10^{-4}$ Pa at 20°C
FMC = 8 $x10^{-5}$ Pa at 25°C

Henry's Law Constant:
Arysta = 1.58 $x10^{-4}$ $Pa.m^3$/mol at 20°C
FMC = 5 $x10^{-5}$ $Pa.m^3$/mol at 25°C

Solubility in Water:
Arysta = 315 mg/l at 19.5 ± 2.0°C (no effect of pH)
FMC = 322 mg/l at 20.0 ± 0.5°C (no effect of pH)

Solubility in Organic Solvents:
Arysta, at 20°C (g/l):

n-hexane:	0.1
xylene:	7.8
1,2-dichloroethane:	106.5
methanol:	71.0
acetone:	107.0
ethyl acetate:	66.9

FMC, at 20°C (g/l):

n-hexane:	0.13
xylene:	8.0
1,2-dichloroethane:	91.0
methanol:	72.8
acetone:	103.4
ethyl acetate:	56.1

Density:
Arysta = 1.228 g/cm^3 (D420) (98.2%)
FMC = 1.290 g/cm^3 (D422) 99.3%)

Dissociation Constant (pKa):
Arysta = no pKa in environmentally relevant pH range
FMC = no pKa in environmentally relevant pH range

Log Pow:
Arysta = 1.8 at 20°C (no effect of pH)
FMC = 1.62 at 22 °C (no effect of pH)

Hydrolysis Rate:
Half-life (days) at 25°C:

Arysta		FMC	
pH 4	stable	pH 7	28
pH 7	45.7	pH 7.5	9.1
pH 9	0.1	pH 8	2.7

UV/VIS Absorption (max.):
Arysta:
In neutral methanol: λmax 276 nm; ε = 2.80 $x10^3$ l/mol/cmat λ 290 nm; ε = 2.51 $x10^2$ l/mol/cm
In acidic methanol: No significant difference in spectrum
In alkaline methanol: Spectrum differs from that in neutral/acidicconditions (λmax 243 and 291) due to carbofuran degradation.

FMC:
In neutral methanol: λmax 277 nm; ε = 3.28 $x10^3$ l/mol/cm at λ 290 nm; ε = 500 l/mol/cm
In acidic methanol: No significant difference in spectrum
In alkaline methanol: Spectrum differs from that in neutral/acidic conditions (λmax 245 and 292) due to decomposition

Photostability (aqueous, sunlight):
Arysta:
pH 5, 22°C, DT50 = 33 days (under Suntest conditions)

FMC:
min. DT50 >126 days for summertime at latitude 30°, 40° and 50° (calculated assuming ϕ = 1)

Quantum yield of direct phototransformation in water at λ >290 nm:
Arysta: ϕ = 0.0015
FMC: direct photolysis is considered to be an insignificant process; no further testing is required

Carbofuran from both Arysta and FMC is non-flammable and non-explosive.

EFSA (2009): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report (2009) 310, 1-132.
http://www.efsa.europa.eu/en/efsajournal/doc/310r.pdf

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report 90, p. 1-88.
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3.2.2 Description of toxicological properties of the chemical

Absorption, distribution, excretion and metabolism in mammals:

Carbofuran is rapidly and completely absorbed and excreted in the rat (32 hours after dosing, 83% of the administered dose was excreted, and 96 hours after a dose, 92% and <4% were excreted in urine and faeces, respectively). In man, the two formulations have a dermal absorption value of 10%. Distribution is rapid, with the liver having the maximum concentration after 1 hour, and accumulation does not occur. Carbofuran is metabolized to form 3-hydroxyl-carbofuran (3-OH-carbofuran) and then glucuronic acid, of which the latter is excreted in the bile. Enterohepatic recirculation may occur. Hydrolysis and hydroxylation of 3-OH-carbofuran also yield 3-OH-carbofuran-7-phenol and 3-keto-carbofuran, respectively, the latter is subsequently hydrolysed to 3-ketocarbofuran-7-phenol. These three metabolites are conjugated and excreted primarily in the urine. Oxidation of carbofuran to N-OH-methylcarbofuran also occurs, which is then hydroxylated to 3-OH-N-OH-methyl carbofuran and then carbon dioxide, which is excreted in expired air.

Acute Toxicity:

Carbofuran is of high acute oral toxicity, of moderate acute dermal toxicity and of high acute inhalation toxicity.

LD50 (male and female rats, oral) 7 mg/kg bw (85%, Furadan 85 DB)

LD50 (rat, dermal) 1000-2000 mg/kg bw

LD50 (male and female rats, inhalation, number of hours exposed not specified) 0.05 mg/l (approx. 13.5 mg/kg bw) (85%)

Irritation & Sensitisation:

Carbofuran is classed as not irritating to the skin and eyes and is not a skin sensitiser. However, mortality has been reported following instillation of 0.1 g to the eyes.

Genotoxicity:

Carbofuran is positive in *in vitro* studies, but negative in *in vivo* studies. *In vitro* results were negative for the Ames test and V79 cell line assay using carbofuran from Arysta, but were positive for the Ames test and mouse lymphoma assays, with and without S9 metabolic activation, for carbofuran from FMC.

In vivo results were negative for the micronuclei assay using mouse bone marrow cells for carbofuran from Arysta and in chromosomal aberration assays for carbofuran from FMC.

Short-term Toxicity:

Rabbits (strain and sex unspecified, dermal, 21 days): NOAEL = 25 mg/kg bw/day (brain AChE inhibition). Lowest relevant dermal NOAEL

Rats (strain and sex unspecified, oral gavage, 60 days): NOAEL = 0.1 mg/kg bw/day (clinical signs of neurotoxicity, testicular damage and sperm impairment)

Dogs (strain and sex unspecified, dietary, 4 week): NOAEL = 5 ppm, i.e. 22 mg/kg bw/day (clinical signs and decreased erythrocyte AChE activity)

Dogs (strain and sex unspecified, dietary, 90 days): LOAEL = <10 ppm, i.e. 0.41 mg/kg bw/day (clinical signs of neurotoxicity and red blood cell AChE inhibition)

Dogs (strain and sex unspecified, oral gelatin capsules, 1 year): NOAEL = 0.1 mg/kg bw/day (clinical signs of neurotoxicity and transient red blood cell AChE inhibition). Lowest relevant short-term NOAEL.

Dogs (strain and sex unspecified, dietary, 1 year): NOAEL = 0.25 mg/kg bw/day (testicular degeneration)

Long-term toxicity and Carcinogenicity:

No carcinogenic potential was observed in four chronic studies (two in rat and two in mice). Tumours observed in the studies were considered to be spontaneous and unrelated to carbofuran treatment.

Rats (strain and sex unspecified, dietary, 2 years): NOAEL = 0.462 mg/kg bw/day (reduced bodyweight, reduced food efficiency and reduced red blood cell and brain AChE). Lowest relevant long-term NOAEL.

Reproductive Toxicity:

Rat (strain unspecified, dietary, 2 generation reproduction study, Arysta):

Reproduction NOAEL = (20 ppm) 2.9 mg/kg bw/day (decreased body weight and survival of pups)

Parental NOAEL = (20 ppm) 1.2 mg/kg bw/day (decreased body weight gain and food consumption)

Rat (strain unspecified, dietary, 3 generation reproduction study, FMC):

Reproduction & parental NOAEL = 1.2 mg/kg bw/day (decreased body weight and pup survival)

Rat (strain unspecified, oral gavage, developmental study):

Developmental NOAEL = 1 mg/kg bw/day (decreased pup body weight)

Maternal NOAEL = 0.1 mg/kg bw/day (clinical signs of neurotoxicity and mortality)

Rabbit (strain unspecified, oral gavage, developmental study):

Developmental and maternal NOAEL = 0.5 mg/kg bw/day (clinical signs of neurotoxicity)

Neurotoxicity:

Rat (strain unspecified, post natal day 11, oral, acute neurotoxicity):

LOAEL = 0.03 mg/kg bw (brain AChE inhibition in pups, effects at lowest dose),

NOAEL for pups extrapolated from LOAEL = 0.015 mg/kg bw/day

NOAEL for adults = 0.03 mg/kg bw/day

Hen (strain unspecified, 28 days, route unspecified, delayed neurotoxicity): NOAEL = 0.5 mg/kg bw/day (no effects observed)

Rat (strain and sex unspecified, dietary, 13 weeks):

Neurotoxicity NOAEL = 50 ppm (3.2 mg/kg bw/day) (clinical signs of neurotoxicity and unspecified FOB parameters)

Safety Values (EFSA, 2009):

EU Risk Assessment Acceptable Daily Intake (ADI) = 0.00015 mg/kg bw/day. This is based on the LOAEL of 0.03 mg/kg bw/day in pups on post natal day 11 from the acute neurotoxicity study in rats for brain AChE inhibition. An uncertainty factor of 200 to account for inter- and intra-species variation, and to extrapolate to a NOAEL was applied.

EU Risk Assessment Provisional Acceptable Operator Exposure Level (AOEL) = 0.0003 mg/kg bw/day. This is based on the NOAEL of 0.03 mg/kg bw/day in adults from the acute neurotoxicity study in rats for brain AChE inhibition. The adult NOAEL was considered to be the most representative value for exposure to carbofuran for operators. An uncertainty factor of 100, to account for inter- and intra-species variation, was applied.

EU Risk Assessment Provisional Acute Reference Dose (ARfD) = 0.00015 mg/kg bw/day. This is based on the LOAEL of 0.03 mg/kg bw/day in pups on post natal day 11 from the acute neurotoxicity study in rats for brain AChE inhibition. An uncertainty factor of 200 to account for inter- and intra-species variation, and to extrapolate to a NOAEL was applied.

Previous safety values are provided below for completeness (EFSA, 2006).

EU Risk Assessment Provisional Acceptable Daily Intake (ADI) = 0.001 mg/kg bw/day. This is based on the NOAEL of 0.1 mg/kg bw/day from the 1 year oral dog study for clinical signs of neurotoxicity and transient red blood cell AChE inhibition and the NOAEL of 0.1 mg/kg bw/day from the 60 day rat oral study for clinical signs of neurotoxicity, testicular damage and sperm impairment. An uncertainty factor of 100, to account for inter- and intraspecies variation, was applied.

EU Risk Assessment Provisional Acceptable Operator Exposure Level (AOEL) = 0.001 mg/kg bw/day. This is based on the NOAEL of 0.1 mg/kg bw/day from the 1 year oral dog study for clinical signs of neurotoxicity and transient red blood cell AChE inhibition and the NOAEL of 0.1 mg/kg bw/day from the 60 day rat oral study for clinical signs of neurotoxicity, testicular damage and sperm impairment. An uncertainty factor of 100, to account for inter- and intraspecies variation, was applied.

EU Risk Assessment Provisional Acute Reference Dose (ARfD) = 0.001 mg/kg bw/day. This is based on the maternal NOAEL of 0.1 mg/kg bw/day for clinical signs of neurotoxicity and mortality from the rat developmental study and an uncertainty factor of 100. Although the uncertainty factor of 100 was deemed provisional at one stage due to possible reproductive effects, although not formalised, this has been decided to be sufficient due to new additional data being received and assessed.

EFSA (2009): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report (2009) 310, 1-132.

http://www.efsa.europa.eu/en/efsajournal/doc/310r.pdf

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report 90, p. 1-88.

http://www.efsa.europa.eu/en/efsajournal/doc/90r.pdf

3.2.3 Description of ecotoxicological properties of the chemical

Soil: Variable results have been obtained from different laboratory degradation experiments, which indicate that carbofuran may be of low to high persistency in soil (lab DT_{50} = 5.7 - 387 days, field DT_{50} = 1.3 - 27 days). Field studies have indicated that 3-OH-carbofuran, 3-keto-carbofuran and carbofuran-7-phenol are

formed, with some levels being reported as 3% of the total residue (TR), 20% TR and <LOD, respectively. EU field trials have indicated that the half-life of carbofuran (as a metabolite of carbosulfan) is 1.3 - 27 days. However, US field studies (at a similar climate compared to the EU) indicate that the half-life for carbofuran as the parent compound is 5-121 days. Only the EU studies were considered applicable. A 56 day laboratory study under dark aerobic conditions at 20°C and 10°C examined the metabolism of carbofuran in four soils. No metabolites over 10% AR were detected in the study performed at 20°C, however, at 10°C 3-keto-carbofuran reached a 7.7% AR. Minor uncharacterised metabolites were detected at <2.5% AR, unextractable residue was up to 57.7% and mineralisation was 66% AR after 120 days. A second study under dark aerobic conditions at 25°C used a sandy loam soil. 3-keto-Carbofuran peaked at 12.41% AR after 181 days, with minor metabolites being 3-OH-carbofuran (maximum 1.32% after 122 days), 3-keto-7-phenol and carbofuran-7-phenol. Another aerobic metabolism study reported that 3-OH-carbofuran and carbofuran-7-phenol reached maximums of 0.9% AR and 9% AR, respectively, after 184 days. The same metabolites were also detected in an aerobic/anaerobic study; after the aerobic phase, 3-keto-carbofuran reached a maximum of 6.2% AR. An anaerobic soil study under dark conditions at 20°C found that after 28 days, carbofuran-7-phenol was the major metabolite at a maximum of 62.9% AR and other minor unspecified metabolites were reported. After 120 days, mineralisation was low (CO_2 6.2% AR) and bound residues reached a maximum of 62.7% AR. Although conflicting results regarding photolysis have been reported, it is concluded that photolysis in soil does not occur (as study limitations are reported for the results of the conflicting study). Based on a K_{oc} of 17-28 ml/g, carbofuran is classified as being of very high mobility in soil. Additionally, an aged column leaching study reports that carbofuran, 3-keto-carbofuran and carbofuran-7-phenol are mobile and may leach.

Water: In water, hydrolysis of carbofuran is extremely dependent on pH; half-lives of none, 28-45.7 days and 0.1 days were observed under acidic (pH 4), neutral (pH 7) and alkaline (pH 9) conditions, respectively, at 25°C. In all cases, the major metabolite was carbofuran-7-phenol. Photolysis does not significantly occur and no indication of ready biodegradation is apparent. A 102 day water sediment dissipation study showed that under acidic conditions, degradation of carbofuran occurred with a half-life of 70 days, 32.8% AR occurred as bound residues and mineralisation was low. Half-lives of 6.9 – 8.5 days in the water phase were reported from dark aerobic systems under neutral or alkaline conditions, with half-lives of 9.0 - 11.6 days being reported for degradation in the whole system. Carbofuran-7-phenol (maximum 12% AR after 4 days) was the only major metabolite in the water phase and in the sediment, only carbofuran exceeded levels of 10% AR. Minor unspecified metabolites were identified (max. 5.9% AR). The maximum amount of bound residues at the end of the study (after 120 days)

was 74-78% AR.

Air: In air, long range transport of carbofuran is not expected. At environmental temperatures (20-25°C), carbofuran has a vapour pressure of 1 $x10^{-5}$ – 2.25 $x10^{-4}$Pa, a Henry's Law constant of 5 $x10^{-5}$ – 1.58 $x10^{-4}$ Pa.m³/mol and a photochemical degradation half-life of <5 hours.

Bioaccumulation: Maximum BCFs for carbofuran have been reported to be 3.8 (fillet), 22 (viscera) and 12 (whole fish), which indicate it is unlikely to bioaccumulate. This is supported by the rapid clearance time CT_{50} (1.4 days). Indeed, the level of residues in organisms after the 14 day depuration phase is <5% (whole fish).

Ecotoxicology

• Earthworm
Acute toxicity
LC_{50} = 4487 mg Diafuran 5G/kg dry soil
LC_{50} >1000 mg Furadan 5G/kg dry soil

Reproductive toxicity
NOEC <16.8 mg Diafuran 5G/kg dry soil

• Bacteria
Nitrogen mineralisation:
No adverse effects of Furadan 5G at 0.8 and 4 mg carbofuran/kg soil after 28 days

Carbon mineralisation:
No adverse effects of Furadan 5G at 0.8 and 4 mg carbofuran/kg soil after 28 days

• Freshwater species
The data below are for the most sensitive species from each group:

Bluegill sunfish (*Lepomis macrochirus*)
96 hours semi-static LC_{50} = 0.18 mg/l

Sheepshead minnow (*Cyprinodon variegatus*)
35 day fish early life stage NOEL = 0.006 mg/l

Water flea (*Daphnia magna*)
48 hours static EC_{50} (mortality) = 0.0094 mg/l

Water flea (*Daphnia magna*)
21 days semi-static NOEC (reproduction) = 0.008 mg/l

Water flea (*Ceriodaphnia dubia*)
7 days semi-static NOEC (reproduction) = 0.00016 mg/l

Scud (*Gammarus fasciatus*)
96 hours static LC_{50} = 0.0028 mg/l

Green algae (*Pseudokirchneriella subcapitata*)
72 hours static E_bC_{50} (biomass) = 6.5 mg/l

Green algae (*Pseudokirchneriella subcapitata*)
72 hours static E_rC_{50} (growth) = 19 mg/l

• Arthropod species
Ground beetle (*Poecilus cupreus*), adults
Diafuran 5G 12 kg/ha = 20% mortality

Beetle (*Aleochara bilineata*), adult females
Diafuran 5G 12 kg/ha = 100% mortality

Beetle (*Aleochara bilineata*), adults
Diafuran 5G 12 kg/ha = 4.5% mortality & 60.4% reduction in parasitism rate

Beetle (*Aleochara bilineata*), adults
Furadan 5G 1-10 kg/ha LD_{50} = 3.58 g/ha

Thin legged wolf spiders (*Pardosa* sp.), adults and sub-adults
Diafuran 5G 12 kg/ha = 100% mortality

Thin legged wolf spiders (*Pardosa* sp.), adults and sub-adults
Diafuran 5G 12 kg/ha = 13.3% mortality & 5.2% increase in food consumption

Thin legged wolf spiders (*Pardosa* sp.), adults and sub-adults
Furadan 5G 3.2-32 kg/ha LD_{50} = 2.7 kg/ha

Predatory mite (*Typhlodromus pyri*), protonymphs
Carbofuran 1.8-18 g/ha LD_{50} = 3.65 g/ha

Cereal aphid parasite (*Aphidius rhopalosiphi*), adults
Carbofuran 1-100 g/ha LD_{50} = 2.68 g/ha

• Marine species -

EFSA (2009): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report (2009) 310, 1-132. http://www.efsa.europa.eu/en/efsajournal/doc/310r.pdf EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran. EFSA Scientific Report 90, p. 1-88. http://www.efsa.europa.eu/en/efsajournal/doc/90r.pdf

SECTION 4 DESIGNATED NATIONAL AUTHORITY

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Date, signature of DNA and official seal: 7.5.2012 EUROPEAN COMMISSION DG ENV.

PLEASE RETURN THE COMPLETED FORM TO:

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Viale delle Terme di Caracalla
00100 Rome, Italy
Tel: (+39 06) 5705 3441
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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.