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

Country: Canada

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 Name: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate CAS Name: 2,3-dihydro-2,2-dimethyl-7-benzofuranyl N-methylcarbamate PIN Name: 2,2-dimethyl-2,3-dihydro-1-benzofuran-7-yl methylcarbamate
1.3	Trade names and names of preparations	Carbofuran Technical Furadan 480 Flowable Systemic Insecticide Furadan 480 F Systemic Liquid Insecticide
1.4	Code numbers	
1.4.1	CAS number	1563-66-2
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 ☒ 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

Sale of pesticides containing carbofuran was prohibited in Canada effective December 31, 2010. The use of products containing carbofuran was prohibited after December 31, 2012. Carbofuran products can no longer be legally used in Canada.

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

Pest Management Regulatory Agency, Health Canada. 2010. Re-evaluation Decision RVD2010-16: Carbofuran.

2.2.3 Date of entry into force of the final regulatory action

December 31, 2012

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 was used to control a broad range of insect pests on a variety of agricultural crops. It was applied to canola, mustard, sunflower, corn (sweet, field and silage), sugar beet, green pepper, potato, raspberry and strawberry using conventional ground equipment; and by aerial application to corn (field, silage and sweet), canola and mustard.

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 registered formulations containing carbofuran and all registered uses of this active ingredient were prohibited.

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

Not applicable

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

Pest Management Regulatory Agency, Health Canada. 2009. Proposed Re-evaluation Decision PRVD2009-11: Carbofuran.

Pest Management Regulatory Agency, Health Canada. 2010. Re-evaluation Decision RVD2010-16: Carbofuran.

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

Based on the label directions of carbofuran products that were registered at the time of the review, use of the pesticide carbofuran posed an unacceptable risk to workers conducting certain mixing, loading, applying or post-application activities. An aggregate dietary risk assessment demonstrated that exposure to carbofuran from food and drinking water was unacceptable. Therefore, carbofuran does not meet Health Canada's current standards for human health protection.

Expected effect of the final regulatory action

Reduction of risk from the use of pesticides containing carbofuran.

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

Based on the label directions of carbofuran products that were registered at the time of the review, use of the pesticide carbofuran posed an unacceptable risk to terrestrial and aquatic organisms, and therefore does not meet Health Canada's current standards for environmental protection.

Additionally, thirty three environmental incident reports from the United States and Canada were considered during the review of carbofuran, and indicated that exposure to carbofuran under the registered use pattern resulted in avian, small wild mammal and bee mortality.

Expected effect of the final regulatory action

Reduction of risk from the use of pesticides 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	Not applicable	2013*
imported	Not applicable	2013*
exported	Not applicable	2013*
used	Not applicable	2013*

*: For pesticides containing carbofuran, the last date of sale by registrants was December 31, 2010. Use of the pesticide carbofuran was prohibited after December 31, 2012.

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

Health and environmental risks are likely to be relevant in other countries with similar carbofuran use pattern.

2.5.3 Other relevant information that may cover:

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

Not applicable

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

Registered alternatives are available for some uses of carbofuran; however, for canola, mustard, raspberry, strawberry and sugar beet, there are no registered (or viable) alternative active ingredients to carbofuran for the control of certain pests. References: Pest Management Regulatory Agency, Health Canada. 2009. Proposed Re-evaluation Decision PRVD2009-11: Carbofuran.

Pest Management Regulatory Agency, Health Canada. 2010. Re-evaluation Decision RVD2010-16: Carbofuran.

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

Not applicable

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

Not applicable

SECTION 3 PROPERTIES

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

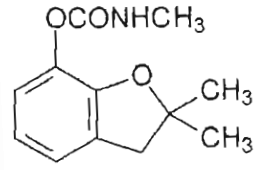
International classification systems e.g. WHO, IARC, etc.	Hazard class
IARC	Group 1 Acetylcholinesterase (AChE) inhibitors, 1A Carbamates

Other classification systems e.g. EU, USEPA	Hazard class
Classification of the USEPA according to the USEPA's 2007 Reregistration Eligibility Decision for Carbofuran	Acute oral toxicity category I: Highly acutely toxic Acute dermal toxicity category III: Slightly acutely toxic Acute inhalation toxicity category I: Highly acutely toxic Acute eye irritation category III: Minimal irritation Primary dermal irritation category IV: Mild or

	slight irritation Skin sensitization: Non sensitizer

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Structural Formula	
Molecular Formula	$C_{12}H_{15}NO_3$
Molecular Weight	221.3
Melting Point	153-154 °C;
Vapour Pressure	0.031 mPa (20 °C); 0.072 mPa (25 °C)
Henry's Law Constant	2.50×10^{-10} atm·m^3·mol^{-1}
Kow logP	1.52 (20 °C)
Density	1.18 (20 °C)
Solubility	In water 320 (20 °C), 351 (25 °C) (both in mg/L). In dichloromethane >200, isopropanol 20-50, toluene 10-20 (all in g/L, 20 °C).
Stability	Unstable in alkaline media. Stable in acidic and neutral media

Reference

The Pesticide Manual, Thirteenth Edition, 2004.

3.2.2 Description of toxicological properties of the chemical

In acute toxicity studies, carbofuran was highly toxic via the oral route of exposure in rats but showed low dermal toxicity. Acute inhalation studies were not available. Carbofuran was a minimal eye irritant and was not a dermal sensitizer. The acute effects observed in oral studies were typical for cholinesterase inhibition: ataxia, salivation, lacrimation, exophthalmos, hyperpnea, cyanosis and generalized tremors. As with other carbamate compounds, carbofuran's cholinesterase-inhibiting effect is short-term and reversible.

In repeat-dose dietary studies in various species (mouse, rat and dog), the dog appeared to be the most sensitive species with respect to cholinergic symptoms. Cholinesterase inhibition was seen in all species with the mouse being the least sensitive. Inhibition of cholinesterase activity is also seen via the dermal route of entry in the rabbit. Repeat-dose inhalation studies were not available. No gender sensitivities were seen in repeat-dose dietary studies. Additional effects

noted in the repeat-dose dietary studies include: a decrease in weight gain in mice and rats and testicular effects in dogs. Rodent studies highlight the differences between gavage and dietary dosing as animals tolerated chronic dietary dose-levels that were equivalent to or even exceeded the LD_{50}s in acute gavage studies. Repeat-dose dietary studies in the rat and dog did not indicate that an increase in the duration of dosing resulted in increased toxicity with respect to cholinesterase activity and/or effects.

Although no guideline acute neurotoxicity study was available, other published studies highlighted the short-acting effects typically associated with carbamate inhibitors of cholinesterase.

Subchronic neurotoxicity studies (dietary) showed clinical signs, decreased motor activity and altered neurological functioning but lacked cholinesterease measurements. Results from the chronic rat study suggest that cholinesterase inhibition was occurring at the levels causing the neurological impairment. In a developmental neurotoxicity study (dietary), doses high enough to cause neonatal death, marked growth retardation and developmental delays did not cause persistent neurological effects. No evidence of neuropathology was noted in any available studies.

Assessments of mutagenic potential in a variety of bacterial and mammalian *in vitro* and *in vivo* studies were performed for carbofuran. Positive results in studies with bacteria have been recorded in *S. typhimurium* (TA 1535 and occasionally TA 98 & TA 1538), while negative results have been reported in other strains of *S. typhimurium*, *S. cerevisiae*, *E. coli and B. subtillis*. In a mouse lymphoma mutagenesis assay, carbofuran displayed weak positive results. Positive evidence from other tests includes the *in vivo* chromosomal aberration assay and micronucleus assay; however, these positive results occurred at levels noted to induce lethality in the acute LD_{50} studies. Negative results were achieved with the Drosophila sex-linked recessive lethal mutation, mitotic recombination in yeast, *in vitro* chromosome aberration, sister chromatid exchange and unscheduled DNA synthesis assays. There is sufficient evidence to support weak mutagenic properties for carbofuran in bacteria and mammalian cells.

Studies for chronic toxicity/carcinogenicity were conducted on mice and rats, and there was no evidence of carcinogenicity.

The developmental toxicity studies in mice, rats and rabbits showed no evidence of teratogenicity and no additional sensitivity of the fetus following *in utero* exposure to carbofuran. Developmental effects in the fetuses included mortality, decreased weight and increased variations alongside maternal observations of mortality, clinical signs and reduced weight gain.

At high dose levels, carbofuran caused sperm and reproductive system damage when fed to either adult male rats or rats exposed *in utero* or during lactation. Degeneration was seen in the

Sertoli cells along with atrophied seminiferous tubules. Disturbed spermatogenesis (decreased sperm count, abnormal sperm morphology and altered testicular enzymes) was noted in the rats. Effects on sperm quantity and quality were observed in carbofuran-treated rabbits. In a one-year dog study, testicular effects were manifested as decreased weight, degeneration of the seminiferous tubules and aspermia. Despite these effects, no reproductive effects were noted in a multigeneration reproductive study. Parental effects were limited to reduced weight gain and food intake whereas offspring effects included reduced weight gain and viability. In view of the findings in the rat, rabbit and dog, carbofuran should be viewed as having some potential for reproductive toxicity.

Reference

Pest Management Regulatory Agency, Health Canada. 2009. Proposed Re-evaluation Decision PRVD2009-11: Carbofuran.

Pest Management Regulatory Agency, Health Canada. 2010. Re-evaluation Decision RVD2010-16: Carbofuran.

3.2.3 Description of ecotoxicological properties of the chemical

Ecotoxicity studies indicated that carbofuran was toxic to a wide range of non-target organisms, including terrestrial invertebrates (acute contact 48-hour lethal concentration on 50% of the population (LD_{50})=0.16 µg a.i./bee; acute contact 14-day LC_{50}=0.28-28.3 mg a.i./kg soil in earthworm), birds (acute oral LD_{50}=0.24-5.6 mg a.i./kg bw; chronic lowest observable adverse effect concentration (LOAEC)< 2.0 mg a.i./kg diet in duck), mammals (acute oral LD_{50}=6.0 mg a.i./kg bw in rat; chronic (reproduction) no observed adverse effect concentration (NOAEC)=1.2 mg a.i./kg in rat), freshwater invertebrates (acute 48-hour LC_{50}=2.6-2700 µg a.i./L and 21-day no observed effect concentration (NOEC)=1.3-9.8 µg a.i./L in waterflea; benthic 10-day LC_{50}=20.9 µg a.i./L in midge), fish (acute 96-hour LC_{50}=88-872 µg a.i./L; 101-day NOEC=24.8 µg a.i./L in rainbow trout), algae (8-10-week NOEC=750 µg a.i./L in green algae), vascular plants (acute NOEC>10,000 µg a.i./L), amphibians (48-hour LC_{50}=11,226 µg a.i./L in bog frog), marine/estuarine invertebrates (acute 96-hour LC_{50}=2.7 - >1000 µg a.i./L; 28-day NOEC=0.4 µg a.i./L in mysid shrimp) and marine/estuarine fish (acute 96-hour LC_{50}=33-386 µg a.i./L; 35-day NOEC=2.6 µg a.i./L in sheepshead minnow).

Reference

Pest Management Regulatory Agency, Health Canada. 2009. Proposed Re-evaluation Decision PRVD2009-11: Carbofuran.

Pest Management Regulatory Agency, Health Canada. 2010. Re-evaluation Decision RVD2010-16: Carbofuran.

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Pest Management Regulatory Agency
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Telefax	1-613-736-3659
E-mail address	Trish.MacQuarrie@hc-sc.gc.ca

Date, signature of DNA and official seal: July 3, 2014

PLEASE RETURN THE COMPLETED FORM TO:

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00153 Rome, Italy
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E-mail: pic@pic.int

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.