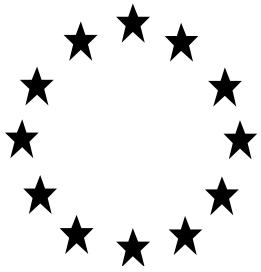
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



Diflubenzuron

Product-type 18 (insecticides, acaricides and products to control other arthropods)

21 September 2012

Annex I - Sweden

Diflubenzuron (PT 18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 21 September 2012 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of diflubenzuron as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I to the Directive.

Diflubenzuron (CAS no. 35367-38-5) was notified as an existing active substance, by Crompton Europe B.V (now Chemtura Europe Limited), hereafter referred to as the applicant, in product-type **18**.

Commission Regulation (EC) No 2032/2003 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 5(2) of that Regulation, Sweden was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Diflubenzuron as an active substance in Product Type 18 was 30 April 2006, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 28 April 2006, Sweden competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 27 October 2006.

On 19 November 2007 the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report (CAR). The Commission made the report available to all Member States by electronic means on 22 November 2007. The competent authority report included a recommendation for the inclusion of Diflubenzuron in Annex I to the Directive for PT **18**.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 20 December 2007. This

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of Diflubenzuron in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 21 September 2012.

In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 21 September 2012.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Diflubenzuron in Annex I to Directive 98/8/EC for product-type **18**. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type **18** that contain Diflubenzuron. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing Diflubenzuron for the product-type **18**, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is, however, subject to:

i. compliance with the particular requirements in the following sections of this assessment report;

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC; and

3 http://ec.europa.eu/comm/environment/biocides/index htm

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

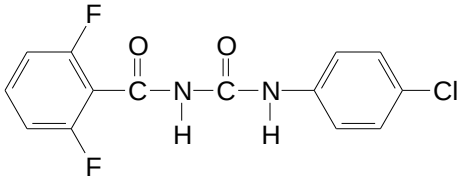
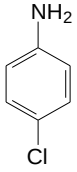
Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity

CAS-No.	35367-38-5
EINECS-No.	252-529-3
Other No. (CIPAC, ELINCS)	CIPAC-No: 339
IUPAC Name	1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea
CA Name	N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide
Common name, synonyms	ISO common name: diflubenzuron Development code No: DU 112307, PH 60-40 and TH-6040
Structural formula	
Molecular formula	$C_{14}H_9ClF_2N_2O_2$
Molecular weight (g/mol)	310.7
Purity of a.s.	960 g/kg
Impurities	Technical diflubenzuron contains one impurity which is considered as relevant (see below). The information on the other impurities are found in the Confidential Annex to the CAR. Relevant impurity Chemical name: 4-chloroaniline Common name: PCA CAS-No.: 106-47-8 EC-No.: 203-401-0 Molecular wieght: 127.6 g/mol Structural formula:  Maximum content: **0.03 g/kg (30 ppm)**

Regulation (EC) No 1272/2008 Annex VI Table 3.1				
Classification		Labelling		
Hazard class and Category Codes	Hazard Statement Code(s)	Pictogram Signal Word Code(s)	Hazard Statement Code(s)	Supp. Hazard statement code(s)
Carc. 1B	H350	GHS06	H350	

	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H317 H400 H410	GHS08 GHS09 Dgr	H331 H311 H301 H317 H410	
	Regulation (EC) No 1272/2008 Annex VI Table 3.2				
	Classification	Risk phrases	Safety phrases	Indication(s) of danger	
	Carc. Cat. 2; R45 T; R23/24/25 R43 N; R50-53	45 23/24/25 43 50/53	53 45 60 61	T N	
Additives	No additives				
Representative biocidal product	Dimilin GR-2 (a granule-formulation for direct application containing 2% w/w diflubenzuron. It should be classified for its content of citric acid; see 2.1.3 below)				

Physico-Chemical Properties

Diflubenzuron as manufactured is a white, dusty powder with a faint odour characteristic of aromatic compounds. Purified diflubenzuron has a melting point of 227.6°C and a boiling point of 257°C at reduced pressure (40 kPa) and its relative density is 1.57. The solubility of diflubenzuron in water is quite low with the highest solubility of 0.32 mg/l at pH 10 (0.1 mg/l at pH 4 and 0.08 mg/l at pH 7). It was shown not to be technically feasible to accurately determine the dissociation constant due to the low solubility in water. However, the solubility in water indicates that diflubenzuron should be considered slightly acidic as the solubility is significantly higher at alkaline pH compared to acidic and neutral pH's. The vapour pressure is $\leq 1.2 \times 10^{-7}$ Pa at 25°C and the Henry's Law Constant of $\leq 4.7 \times 10^{-4}$ $Pa.m^3.mol^{-1}$ indicates that volatilisation is not expected to significantly contribute to the dissipation of diflubenzuron in the environment. The Log P_{ow} was only tested at pH 3 using the HPLC-method, as that condition showed good correlation between retention times and literature Log P_{ow} data. The obtained log P_{ow} of 3.89 indicates that diflubenzuron may bioaccumulate and as the solubility in water is higher at alkaline pH, the result could be seen as a worst case log P_{ow}. In addition the log P_{ow} at pH 3 was also determined for the metabolites 4-chlorophenylurea (CPU) and 2,6-difluorobenzoic acid (DFBA) as 1.14 and -0.02 respectively. For both CPU and DFBA the used test conditions (pH 3) are considered acceptable as CPU cannot dissociate and as DFBA is predominantly present in ionised form at pH ≥3 (pKa; open literature value).

Diflubenzuron is soluble in polar organic solvents and less so in non polar ones. Diflubenzuron is not highly flammable, auto-flammable, explosive or oxidizing.

Analytical methods

Acceptable analytical methods, with respect to validation data, were provided for all required matrices.

The content of diflubenzuron in the technical material is determined by HPLC-UV using simple external calibration or external calibration relative to an internal standard. The analytical method for determining the content of the relevant impurity PCA in the technical material is based on HPLC-UV and it is acceptable and with a sufficient LOQ. The analytical method for the determination of the remaining impurities in the technical material are also acceptable and are further described in the Confidential Annex to the CAR. The content of diflubenzuron in the representative formulation Dimilin GR-2 is determined by HPLC-UV, with external calibration relative to an internal standard. No method has been provided for analysis of the relevant impurity PCA in the biocidal product and this should be considered for product authorisation at Member State level.

The contents of diflubenzuron and the relevant metabolites CPU and DFBA in soil are determined by LC-MS/MS using one transition, with a LOQ of 0.05 mg/kg for all species. The content of diflubenzuron in air is quantified by means of LC-MS/MS using two ion transitions, with a LOQ of 0.6 µg/m^3, which is considered acceptable with respect to the AEL of 0.0066 mg/kg bw/day. In the original dossier, a method for the determination of diflubenzuron and the relevant metabolites CPU and DFBA in surface water based on LC-MS/MS (one ion transition), with a LOQ of 0.1 µg/l for all species, was provided. The LOQ is acceptable for drinking water and the method is accepted for that purpose. However, the LOQ is not sufficiently low for surface water, for which a LOQ of 0.04 µg/l is required based on the long-term NOEC on *Daphnia magna*. To address this, the applicant submitted during the peer-review of draft final CAR an additional LC-MS/MS method (two ion transitions) for surface water (Wolf, S., 2009) which is validated for diflubenzuron (parent) and confirms a LOQ of 0.04 µg/l for diflubenzuron.

No method is required for the analysis of diflubenzuron residues in food and feeding stuffs of plant origin as the intended use pattern does not result in contact with these matrices. As shown in 2.2.1 below (live stocks and pets) the intended use of diflubenzuron may result in exposure to livestock and an analytical method for monitoring of residues in food and feeding stuffs of animal origin may thus be required. However, this can only be concluded on when a dietary risk assessment has been performed and this should be conducted at the stage of product authorisation at Member State level.

A Method for body fluids and tissues is not required since diflubenzuron is not classified as toxic or highly toxic.

2.1.2. Intended Uses and Efficacy

At the time of application the intended uses were described as control of mosquito larvae in water (i.e. gully-holes and septic tanks in urban, suburban and rural areas and storage containers for garden irrigation) and control of fly larvae in farm buildings or in refuse and waste disposal areas. During the evaluation process the intended uses have been refined and some has also been withdrawn by the applicant mainly as a result of identified risks for the environmental compartments. The intended use upon which inclusion in Annex I is recommended is fly larvae control in indoor poultry farming (hen houses) with the restrictions that the application should be made on dry manure heaps under caged hens. It should be noted that even though the use in hen houses is restricted to certain conditions, this is consistent with current practice within parts of the EU at the time of writing this Assessment Report.

The broad uses in animal houses and uses in water systems have also been considered at risk assessment and included in the CAR for future reference should applications for product authorisation be made for these uses.

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be generally efficacious as an insecticide. However, efficacy data has not been provided for the specific use in poultry farming and this is considered necessary for product authorisation.

2.1.3. Classification and Labelling

Currently there is no harmonised classification and labelling for diflubenzuron according to Annex VI to Regulation (EC) 1272/2008. On the basis of the available data the RMS proposes the following classification and labelling for diflubenzuron:

Classification against criteria in Regulation (EC) No 1272/2008				
Classification		**Labelling**		
Hazard class and Category Codes	**Hazard Statement Code(s)**	**Pictogram Signal Word Code(s)**	**Hazard Statement Code(s)**	**Supp. Hazard statement code(s)**
STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H373 H400 H410	 Warning	H410 H373	
Precautionary Statement Prevention		P273, P260		
Precautionary Statement Response		P391, P 314		
Precautionary Statement Disposal		P501		

Classification according to criteria in Directive 67/548/EEC			
Classification	**Risk phrases**	**Safety phrases**	**Indication(s) of danger**
Xn N	R48/20/21/22 R50/53	S60-S61	Harmful Dangerous for the environment

The RMS intends to prepare an Annex VI-dossier and submit it to ECHA in order for a harmonized classification and labelling for diflubenzuron to be established in accordance with Regulation EU No. 1272/2008. It should be noted that the applicant disagrees with the proposed R48 classification.

The following classification and labelling is proposed by the RMS for the representative biocidal product Dimilin GR-2 on the basis of the available data and according to the criteria in Regulation (EC) No 1272/2008 and Directive 1999/45/EC, respectively:

Classification according to criteria in Regulation (EC) No 1272/2008				
Classification		Labelling		
Hazard class and Category Codes	Hazard Statement Code(s)	Pictogram Signal Word Code(s)	Hazard Statement Code(s)	Supp. Hazard statement code(s)
Aquatic Acute 1 Aquatic Chronic 1 Irritating to eyes (Category 2)	H400 H410 H319	  Warning	H410 H319	
Precautionary Statement Prevention		P273, P264, P280		
Precautionary Statement Response		P391 P305 + P351 + P338 P337 + P313		
Precautionary Statement Disposal		P501		

Classification according to criteria in Directive 1999/45/EC			
Classification	Risk phrases	Safety phrases	Indication(s) of danger
Xi N	R36 R50/53	S60-S61	Irritating Dangerous for the environment

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

Toxicokinetics and metabolism

Diflubenzuron is poorly absorbed from the gastro-intestinal tract and, over a dose range of 5 to 100 mg/kg bw in the rat, absorption decreases with increasing dose level. The oral absorption was estimated from urine and faecal ratios in bile-cannulated rats to be approximately 33 %. A high level of non-absorbed diflubenzuron was found in the faeces. Absorbed radioactivity was almost completely removed within 24 to 48 hours. Low residues remained in liver and erythrocytes only. There were no indications that diflubenzuron or its metabolites accumulate in any part or compartment of the rats' body. Excretion is primarily via bile and urine. The major metabolites of diflubenzuron identified in rat urine were 4-chloroaniline-2-sulfate (45% of urine TRR), and n-(4-chlorophenyl) oxamic acid (13% of urine TRR). About 3% of urine TRR was 2'-hydroxy-diflubenzuron. The other 18 metabolites each individually accounted for less than 2% urine TRR. Unchanged parent diflubenzuron was the only residue found in the faeces. Neither 4-chloroaniline (PCA), 4-chlorophenylurea (CPU) nor their n-hydroxyl derivatives were found in rat urine at a limit of detection of 0.4 ppb.

Dermal absorption of diflubenzuron measured in vivo in the rat was 6 %. Absorption through human skin is typically one order of magnitude lower than through rat skin. The rat in vivo value of 6 % dermal absorption is, therefore, considered a conservative estimate of human absorption and, in the absence of human data, is considered appropriate for use in the calculations of operator exposure. For inhalation absorption a default value of 100 % has been used.

Acute toxicity

Diflubenzuron is of low acute toxicity. Diflubenzuron is not irritating to skin or eyes and it is not a skin sensitising substance. However, a major component of the Dimilin GR-2 granule is citric acid. This ingredient is classified as irritating to eyes and therefore Dimilin GR-2 should be classified as Eye Irrit. 2; H319 according to CLP criteria and Xi, R36 ("Irritating to eyes") according to criteria in Directive 67/548/EEC.

Repeated toxicity

Increase of methaemoglobin and sulfhaemoglobin was seen in all longer studies with diflubenzuron, often together with increase in liver and spleen weight and sometimes with histological findings such as liver cell enlargement and iron pigmentation (haemosiderosis). Haemosiderosis in both spleen and liver together with marrow hyperplasia indicates that the formation and degradation of erythrocytes occurs in an abnormal way and that several organs are involved in taking care of dead erythrocytes and preparing new ones. In conclusion, this indicates that diflubenzuron can cause anaemia and RMS suggests that diflubenzuron should be classified as STOT RE 2, H373, "May cause damage to organs through prolonged or repeated exposure" according to CLP and Xn; R48; "Harmful by inhalation, dermal contact and if swallowed" according to the criteria in Directive 67/548/EEC. However, Dimilin-GR2 contains only 2 % diflubenzuron and is, therefore, not classified.

4-chloroaniline, PCA, is known to be a possible metabolite of diflubenzuron and in the toxicological studies with diflubenzuron similar effects are seen as in studies with PCA (e.g. increased levels of methemoglobin and sulfhemoglobin, effects of blood parameters, increased spleen and liver weight, haemosiderosis in spleen and liver and extramedullary hematopoiesis).

PCA has a harmonised classification as carcinogenic, Carc. 1B; H350 and Carc. Cat 2; R45 according to CLP Annex VI in regulation 1272/2008.

Diflubenzuron was included in the Annex I to Directive 91/414/EEC, in July 2008 but confirmatory data was requested. The RMS has evaluated the new data, where two questions regarding PCA toxicity was posed by the Standing Committee, and concludes as follows:

1) Is PCA an *in vivo* mutagen? After having evaluated the micronucleus test, UDS study and Comet Assay, RMS concludes that the answer is yes.

2) Can diflubenzuron be metabolized to PCA in humans? The answer is yes, according to the comparative hepatocyte study with cells from rat, human, goat and pig.

The confirmatory data from the evaluation under 91/414/EEC was discussed during a Technical Meeting on biocides (TM I 2012) and it was concluded that PCA is an intermediate metabolite in diflubenzuron metabolism and that it is an *in vivo* mutagen. Diflubenzuron was not found to be mutagenic in the tests available. The TM also considered that the rat data package covers the risk for humans although the RMS remains not entirely convinced of this. For comments regarding the conclusion that the rat data package also covers the risk for humans please see document II of the competent authority report, section 3.5. under "Mechanism behind the increase of methaemoglobin and the formation of the metabolite PCA".

Genotoxicity

Diflubenzuron has no genotoxic potential.

Carcinogenicity

There is no evidence of carcinogenicity in rats, mice or dogs in long term studies with diflubenzuron.

Reproduction toxicity

Diflubenzuron has no effect on reproduction or fertility.

Neurotoxicity

Specific neurotoxicity testing was not considered necessary as no indication of neurotoxic properties was found in any studies.

Medical data

To the best of the applicant's knowledge, there have been no reports of significant adverse effects from exposure to diflubenzuron or its formulations in workers, i.e. mixers/loaders, applicators, manufacturers or the general public.

Live stock and pets

The biocidal use of Dimilin GR-2 in animal houses may result in exposure of livestock and consequently also in exposure of humans via food of animal origin. Therefore, derivation of a maximum residue level (MRL) and a dietary risk assessment are necessary. Harmonised guidance documents on animal exposure assessment and dietary risk assessment are expected to become available during 2012 and these should be used when authorising Dimilin GR-2 in Member States.

Exposure of pets is not considered in this assessment. Depending on the intended use, this may be a relevant scenario to include in the risk assessment at future authorisations of formulations containing diflubenzuron.

Acceptable daily intake (ADI) and acute reference dose (ARfD)

At the time of writing this assessment report the intended use for fly control is only for poultry farms under caged hens, which is out of reach from the animals, and no ADI needs to be set. However, if, in the future, diflubenzuron is intended for use in animal houses for animals used for food production and, if the animals can be exposed to diflubenzuron (by licking and pecking), an ADI will be needed. The ADI should be 0.012 mg/kg bw/day based upon the NOAEL value of 1.2 mg/kg bw/day from the 91 week mouse study and the application of a 100 fold safety factor.

Diflubenzuron is not acutely toxic and no ARfD needs to be set.

Acceptable Operator Exposure Level (AEL)

The lowest relevant NOAEL for medium-term exposure was 2 mg/kg bw/day in dog, after oral administration of diflubenzuron. The major effect observed at the Lowest Observed Adverse Effect Level (LOAEL) was increased methaemoglobin and sulfhaemoglobin and change in other blood parameters and increase in spleen weight. The proposed $AEL_{medium\text{-}term}$ is based on the NOAEL of 2 mg/kg bw/day, applying a 100-fold safety factor to the relevant dose and adjusting for low oral absorption of 33% which gives an $AEL_{medium\text{-}term}$ of 0.0066 mg/ kg bw/day. AEL_{acute} is based on increase in methaemoglobin and sulfhaemoglobin at 81 mg/kg bw/day (LOAEL) in a 28-day rat study and is 0.13 mg/kg/day (using a safety factor of 200) and $AEL_{long\text{-}term}$ is 0.004 mg/kg bw/day based on a NOAEL of 1.2 mg/kg bw/day from a 91 week mouse study where increased methaemoglobin and sulfhaemoglobin where observed at LOAEL (using a safety factor of 100).

2.2.2. Exposure assessment and risk characterisation

Exposure of manufacturers

Production of diflubenzuron as well as manufacture of Dimilin GR-2 takes place within the EU area. However, exposure of workers at the production/formulation plants is not considered in the risk assessment as it is assumed to be within the scope of other legislation on worker safety.

Exposure of professionals

After the draft CAR had been written the applicant changed the intended use for diflubenzuron. It is now said to be used against mosquito larvae in water systems (gully-holes and septic tanks in urban, suburban and rural areas) and against fly larvae, indoor, in dry manure in poultry farms heaps under caged hens. However, RMS has chosen to leave the calculation where diflubenzuron is used in animal houses (included in the draft CAR) as that will also cover the exposure due to the new intended use. It means that maximally 6 septic tank per days, containing 75000L, could be treated without given worker exposure above the AEL.

Application in animal houses: 1000 m^2 animal house treated with 0.5 g a.s./m^2 causes a worker exposure of 500 g a.s./day.

Application on dry manure in poultry farms: The application area is expected to be less than the 1000 m^2 in the animal house.

Application to septic tank: 4 - 10 septic tanks/day, containing 75000L treated with 1mg a.s./L causes a worker exposure of 300 - 750 g a.s./day.

Application to gully-holes: 800 holes/day, treated with 0.04 g a.s (1 mg a.s./L) causes a worker exposure of 32 g per day.

Product	Workplace operation	PPE	Exposure path	Body dose (mg/kg bw/day)	Exposure as percentage of AEL (0.0066 mg/kg bw/day)	Repeated dose toxicity (NOAEL = 2 mg/kg bw/day)
						MOE
Dimilin GR-2	Control of flies, Scatter granules inside animal house	Eye protection	Dermal + inhalation	0.0153	232%	43
Dimilin GR-2	Control of flies, Scatter granules inside animal house	Eye protection Cotton overall	Dermal + inhalation	0.0114	173%	58
Dimilin GR-2	Control of flies, Scatter granules inside animal house	Eye protection Cotton overall Gloves	Dermal + inhalation	0.0060	91%	110

Incidental exposure of non-professionals/bystanders

Exposure to diflubenzuron after application for all non-users is considered to be negligible. The Dimilin GR-2 granules rapidly dissolve as they react with humidity. The granules are non dusty and diflubenzuron is non-volatile (vapour pressure is less than or equal to 1.2×10^{-7} Pa at 25^{o}C) and therefore there will be no inhalation exposure of bystanders. The risk is negligible after accidental dermal exposure of child visiting an animal house and when a child picks up some non dissolved granules and swallows them. Bystanders are not expected to come into contact with Dimilin GR-2 treated manure heaps or treated water. If some granules would fall on the side of the gully-hole or septic tank the risk scenario is supposed to be covered by the estimations made for the animal house.

At the time of writing the assessment report the intended use for fly larvae is only for manure in poultry farms heaps under caged hens, which is out of reach from the animals (this is the only use that still is acceptable for the environment). If in the future, diflubenzuron is to be considered for use in animal houses for cows and pigs, or other animals used for food production, the following factors have to be considered: re-entering the animal house the animals might lick the floor and accidentally be exposed to diflubenzuron and therefore a dietary risk assessment has to be done at the product authorisation level. Particular attention has to be paid to the metabolite para-chloroaniline (see section 3.5 Repeated dose, under "Mechanism behind the increase in methaemoglobin and the formation of the metabolite PCA".

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

The soil degradation studies, normalized to 12°C, showed that the aerobic DT_{50} for diflubenzuron ranged between 4.9-12.7 days in the studied soils (geometric mean 7.5 days). Four known (DFBA, 2,6-difluorobenzoic acid; CPU, 4-chlorophenylurea; PCA, 4-chloroaniline; DFBAM, 2,6-difluorobenzamide) and two unknown (M7 and M9) metabolites were detected in the aerobic degradation studies. Only two were detected at significant quantities, DFBA and CPU at a maximum of 13.3% and 30.8% of the applied radioactivity after 3 and 7 days, respectively. The geometric mean DT_{50} is 42 days for CPU and 12 days for DFBA (both normalized to 12°C). The degradation to the main metabolites CPU and DFBA, followed by mineralisation to $^{14}CO_2$ and formation of bound residues was shown to be the main dissipation pathway of ^{14}C-diflubenzuron in soil. The first order DT_{50} for diflubenzuron at anaerobic conditions was 84 days (normalized to 12°C) and hence slower than under aerobic conditions. Diflubenzuron is stable towards soil photolysis.

For diflubenzuron the mean K_d for adsorption is 65.2 and the mean K_{oc} value for adsorption is 4609 indicating a low potential for mobility. For the major metabolite CPU, the mean K_d value for adsorption is 3.2 with a corresponding mean K_{oc} value of 245, indicating a weaker sorption of the metabolite compared to the parent. For DFBA no valid studies were available (due to low Koc). Therefore, the Koc data were derived with QSAR estimation techniques (PCKocWin v1.66), resulting in a K_{OC} of 39.6 mL/g.

The aquatic degradation studies showed that the dissipation DT_{50} values for diflubenzuron were 6.1 and 5.3 days (12°C) in the water phase of the two studied water/sediment systems. The DT_{50} for the whole systems was 7.0 and 10.2 days (12°C), in the studied pond and river systems, respectively. Diflubenzuron degrades to CO_2 (38% and 33% after 104 days in the pond and river systems, respectively) and forms non-extractable residues in the sediment (36 % and 44 % after 104 days in the pond and river systems, respectively). The major degradation products were CPU (maximum 31% of applied radioactivity in water and 21% in sediment) and DFBA (maximum of 13 % in water and 3.7% in sediment). Several minor metabolites did not exceed 10 % of the applied radioactivity. The direct photodegradation of diflubenzuron is slow (DT_{50} = 80 days of sunlight at 40°N). Diflubenzuron is stable towards hydrolysis.

Diflubenzuron was not considered readily degradable in a ready biodegradability test (OECD 301).

Diflubenzuron has a very low vapour pressure ($\leq 2 \times 10^{-7}$ Pa at 25ºC) and no significant losses are anticipated through evaporation as a result of the proposed use of diflubenzuron. The atmospheric half-life of diflubenzuron, due to gas-phase hydroxyl radical reactions, was estimated to be 7.9 hours (with 24 hours day and a [OHrad] of 1.5×10^{-6}), respectively 23.7 hours (with a 12 hours day and a [OHrad] of 0.5×10^{-6}, EPI Suite calculations). Therefore, it is not expected that diflubenzuron will be present in air for extended periods and the long range transport and re-deposition of diflubenzuron is expected to be negligible.

The study on bioconcentration in fish had several shortcomings; however, the RMS considers that it is sufficient to give an indication of the BCF. According to Annex VI para. 88 of 98/8/EG, an active substance shall not be included in Annex I if “the bioconcentration factor

(BCF) is greater than 1000 for substances which are ready biodegradable, or greater than 100 for those which are not biodegradable, unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms…". In the present study, the BCF for whole fish was found to be 320 which is above the trigger value, since diflubenzuron cannot be regarded as a readily biodegradable substance. Therefore a further assessment of the possible secondary poisoning of diflubenzuron is needed. This is discussed in DOC II C, section 13.5 of the CAR where it is concluded that the risk for secondary poisoning is low.

2.2.3.2. Effects assessment

Aquatic

The acute toxicity of diflubenzuron to fish is low. The 96-hour LC_{50} value was >0.13 mg/L for fish. Also the acute toxicity of the metabolites CPU and DFBA is low, i.e. the 96-hour LC_{50} values were 70 and >100 mg/L for CPU and DFBA, respectively.

A semi-static prolonged 21 day exposure study with rainbow trout (*Oncorhynchus mykiss*), tested at a nominal exposure concentration of 0.2 mg/L, gave an NOEC of 0.2 mg/L based on mortality, growth rate and a range of other sub-lethal effects observations.

The 48-hour static toxicity test with *Daphnia magna* exposed to diflubenzuron yielded an EC_{50} value of 2.6 µg/L. An embryo-larval study was conducted with *Mercenari mercenaria* (qahogs or venus clams), where no effects were seen at a mean measured exposure concentration of 320 µg/L. The acute toxicity of metabolites CPU and DFBA were determined with *Daphnia magna*. The 48-hour EC_{50} values were 116 and >60 mg/L for CPU and DFBA, respectively. Long-term and reproduction toxicity for aquatic invertebrates was investigated by exposing *Daphnia magna* for 21 days to a concentration range of diflubenzuron in a flow-through study. The NOEC based on reproduction and parental mortality was 0.04 µg/L. A long-term and reproduction toxicity study was performed with *Mysidopsis bahia* (mysid shrimp), and based on reproduction and survival at day 28 the NOEC for mysid shrimps was 0.045 µg/L.

Diflubenzuron has been tested with the green algae, *Selenastrum capricornutum*. No effects were seen on either biomass or growth rate at the exposure concentration tested (0.20 mg as/l). The acute toxicity of metabolites CPU and DFBA were determined with *Selenastrum capricornutum*. The 72-hour EC_{50} values were 30 and 95 mg/L for biomass and growth rate for CPU and >100 mg/L for both biomass and growth rate for DFBA. The diflubenzuron 14-day EC_{50} was determined to be >0.190 mg/L for *Lemna gibba* and the NOEC was 0.190 mg/L.

A littoral enclosure study and a literature review were submitted by the notifier (see CAR Document III-A.7.4.3) in order to refine the aquatic risk assessment. The littoral enclosure study had a number of shortcomings, however. Several important groups of organisms were lacking, or were only present in too low numbers, or were too variable to allow for a meaningful assessment. Additionally, the calculated effect levels were based on nominal concentrations, while measured concentrations were partly much lower. Therefore the RMS does not consider that the submitted littoral enclosure study reduced the uncertainty sufficiently regarding the variation in sensitivity between different species of aquatic chitin producing invertebrates. Neither could the literature review could eliminate these

uncertainties. Weighing all the information of the littoral enclosure study and the literature studies, the Technical meeting II/09 came to the conclusion that the uncertainties are too big to use the studies for the derivation of a PNEC. It therefore considered that the single species long-term Daphnia test is to be used for the derivation of the PNEC; in view of the amount of data available it is regarded appropriate to apply an assessment factor of 10, however. This results in a PNECsw of 0.004 µg/l. The PNECsed was derived by the EPM, which resulted in a PNECsed of 0.4 µg/kg.

Terrestrial

The exposure of honeybees is negligible following the proposed use, but studies were submitted indicating a potential toxicity to honeybee larvae. Submitted data for foliar and soil surface dwelling non target arthropods also indicated a high sensitivity.

In a laboratory study with earthworm, *Eisenia foetida*, the 14-day LC_{50} value of diflubenzuron was determined to be >398 mg/kg ww soil, the NOEC was determined to be 398 mg/kg ww (normalized values to standard organic matter).

The acute toxicity of metabolites CPU and DFBA were determined with *Eisenia foetida*. The 14-day LC_{50} values were 952 and >1390 mg/kg soil ww for CPU and DFBA respectively (not normalized values).). Applying an assessment factor of 1000, the derived PNECs were 952 µg/kg ww for CPU and 1.39 mg/kg ww for DFBA.

There were no effects of diflubenzuron on the short-term respiration of soil microflora at 0.1 mg/kg dw and 1.0 mg/kg dw. Long term soil microflora studies showed no adverse effects on carbon respiration or nitrogen transformation at 1.17 mg a.s./kg ww soil, the highest concentration tested (3 months exposure period). Applying an assessment factor of 100 the resulting PNEC was 11.7 µg diflubenzuron/kg soil ww.

Screening tests were performed on the toxicity of diflubenzuron to plants and fungi, indicating a low toxicity.

Information on what is probably the most sensitive group of organisms is lacking, i.e. soil insects. This has not been addressed by the notifier. Data for terrestrial insects (for surface or foliar dwelling) are available, indicating a high sensitivity. Since this data is based on surface exposure, it is difficult to use it for soil risk assessment, but it clearly indicates that arthropods are very sensitive to diflubenzuron and that an assessment is needed. Lacking such assessment, the PNEC was estimated using the equilibrium partitioning method instead (eq 72 in the TGD), resulting in a PNECsoil of 0.33 µg/kg wet soil.

In order to evaluate the toxic potential of diflubenzuron to birds, various laboratory studies on acute and short-term exposure have been carried out, all indicating a low toxicity (i.e. LD_{50}>5000 mg/kg bw and NOEC 42.7 mg/kg bw d).

STP

The 3-hour EC_{50} value for aerobic waste water bacteria from activated sewage sludge exposed to diflubenzuron was determined to be >1000 mg/L, the NOEC was 1000 mg/l. Applying an AF of 10, this results in a PNEC of 100 mg/L for this compartment.

2.2.3.3. PBT assessment

Degradation data (see above) indicates that diflubenzuron and its breakdown products are unlikely to persist in the environment for long time periods. The BCF was estimated to be 320 for diflubenzuron; even though this study had several shortcomings, it indicates that diflubenzuron cannot be considered as bioaccumulative; furthermore the Log K_{ow} is < 4.5. The toxicity of diflubenzuron to birds is low (NOEC 42.7 mg/kg bw d). The NOEC for freshwater organisms is 0.04 µg/L, indicating that diflubenzuron can be considered as fulfilling the T criterion. However, diflubenzuron should not be regarded as a PBT substance, since it cannot be considered as fulfilling the criteria for persistence or bioaccumulation.

2.2.3.4. Endocrine disruption

Diflubenzuron is not deemed to be an endocrine disruptor on the basis of available information (see Table 5 of EU COMMISSION STAFF WORKING DOCUMENT on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM(1999)706) (http://ec.europa.eu/environment/endocrine/documents/sec_2004_1372_en.pdf)

2.2.3.5. Exposure assessment

The following uses are considered for the environmental risk assessment:

- Control of mosquito larvae in water systems (gully-holes and septic tanks in urban, suburban and rural areas)
- Control of fly larvae: in dry manure in poultry farms (limited to dry manure heaps under caged hens).

Originally, also use in water storage containers for garden irrigation (mosquito control) and use on waste disposal areas (fly control) were intended, claiming these were closed systems that did not lead to environmental exposure. This definition was not accepted by the MS and the uses were withdrawn. Furthermore, the originally intended use in animal houses was narrowed during the evaluation process to the above mentioned use in a special type of poultry farming.

Mosquito control in gully holes

In this scenario exposure was calculated for two example regions in Italy where Dimilin is in use for mosquito control. The exposure was calculated assuming monthly applications during the mosquito season and assuming average rain events representative for Italy in summer. Dimilin is directly applied to every single gully hole and gets transported away during rainfall. In principle there are two different types of sewage systems: combined sewers are designed to transport both rain water runoff and sewage in the same pipes. The mixed water is then treated in a STP. Separate systems transport the rain water in separate sewers through which it is directly drained, sometimes via depuration basins, into surface water bodies. In the exposure calculations, both systems were taken into account. Furthermore, the distribution of Dimilin between the water phase and the sediment phase was taken into account: the major part is

adsorbed to the gully hole sediment, which gets washed out of the gully hole by moderate or heavy rainfalls (20 to 50 mm rain).

For separate systems, PECs up to 0.04 µg/l for surface water and up to 4.4 µg/kg for sediment were calculated (figures for 50 mm rain events, respectively).

For combined systems, PECs up to 0.03 µg/l for surface water and up to 3.5 µg/kg for sediment were calculated (figures for 50 mm rain events, respectively).

For exposure of microorganisms in the STP, a PEC of 0.346 µg/l was calculated.

Following application of municipal sludge to soil, soil concentrations of 0.242 µg/kg wet soil were estimated (concentration after one application; accumulation over several years was not accounted for because of the degradation behaviour of diflubenzuron).

A PEC for groundwater was not calculated, as this is covered by the septic tank scenario which is more worst case with respect to soil.

As the gully hole scenario showed a risk for surface water and sediment for diflubenzuron, it was not considered necessary to calculate for the metabolites in this scenario.

Mosquito control in septic tanks

Dimilin is used for mosquito control in septic tank systems. The mosquitos are supposed to get access to (older) septic tanks via cracks and fissures, so that the notifier claims an application area here for mosquito control. Following Dimilin application to a septic tank, the drain field of the septic tank and possibly the groundwater are exposed. The majority of the applied diflubenzuron remains in the settled sludge of the septic tank, however. As legislation about the disposal of septic tank sludge varies greatly in different regions, it was impossible to calculate exposure for possible disposal sites of this sludge. Thus, only exposure calculations for liquids flowing out of the tank to the drainage field were made. Diflubenzuron concentrations in soil and groundwater were calculated.

For the drainage field, a PEC soil of 0.0377 mg/kg x month was calculated, without taking degradation into account. After 4 month, which was supposed to be the application time during the mosquito season, a PEC of 9.08 µg/kg wet soil was calculated, taking degradation into account.

Groundwater calculations were made with FOCUS Pearl. The groundwater assessment showed no exceeding of the drinking water trigger concentration of 0.1 µg/l for diflubenzuron at any of the FOCUS locations. For the metabolite CPU, however, the limit value was exceeded at two locations (0.17 µg/l in Okehampton and 0.19 µg/l in Piacenza).

Fly control in poultry farming

Dimilin was originally intended for fly control in animal houses. The notifier claims that it has to be used in an integrated concept, together with other means of fly control. The use in animal houses, however, was narrowed during the evaluation process to poultry farms with dry manure processing, as liquid slurry showed to be problematic with respect to risk for soil. The limitation to caging with high rise, deep-pit, is a consequence of the need for dry manure

processing. Even if free range poultry farming is also liquid slurry free, this type of farming could not be included because of data gaps in the human health assessment (see 2.2.1 Live stock and pets). In addition to the limitation to dry manure processing, subsequent composting proved to be necessary to further reduce the content of diflubenzuron in manure, before it is applied to agricultural soil.

Dimilin is applied three times during the fly season. The manure is taken out of the manure pit after one or more production cycles are completed. Thus, the manure is usually kept in the poultry house from 6 month up to a whole year. When the poultry house is cleaned out, the manure undergoes composting. After composting, DFB residues were found to be 0.29% of applied (assuming a hot phase during composting), or 1.8% of applied (assuming no hot phase).

Resulting PIECars-N in soil (initial concentration of diflubenzuron in soil following manure application to arable land according to the EU nitrogen emission standard) were calculated to be 0.016 µg/kg (with hot phase composting) and 0.09 µg/kg (with no hot phase). Without composting, PIECars-N was calculated to be 3.6 µg/kg. After one year, the concentration in soil was 3.5^{-11} µg/kg wet soil and 2.1^{-10} µg/kg wet soil, respectively.

For the metabolite CPU, PECs after one year were 3.8^{-5} µg/kg wet soil and 2.3^{-4} µg/kg wet soil (with and without hot phase composting). The calculations were based on a transformation rate from DFB to CPU of 1, which is a very conservative assumption.

It was not considered necessary to calculate for accumulation over several years, neither for diflubenzuron nor for its metabolite CPU, considering the low concentrations and the degradation behavior.

2.2.3.6. Risk characterisation

The PNECs for the different compartments are summarized in the table below. The PEC/PNEC ratios are listed under the single scenarios.

Table 2.2.3.6.a. Summary of the PNECs of diflubenzuron for the environment.

Compart-ment	Ground water	Surface water	Sediment (EPM)	STP	Terrestrial (soil micro-organisms)	Terrestrial (EPM)*	Terrestrial (birds and mammals)
PNEC	0.1 µg/L	0.004 µg/L	0.4 µg/kg	100 mg/L	11.7 µg/kg ww	0.33 µg/kg ww	No exposure

* The TM II/09 decided that the most sensitive of the terrestrial PNECs should be used

Table 2.2.3.6.b: The PNECs of the metabolites for the terrestrial compartment

Metabolite	**PNEC Terrestrial (Earthworm)**
CPU	952 µg/kg ww
DFBA	1.39 mg/kg ww

Mosquito Control in Gully Holes

This use of diflubenzuron shows a risk for surface water and sediment, both for combined and for separate systems. The shown figures are calculations for rain events of 50 mm. However, even less heavy rain events (from 20 mm) cause diflubenzuron concentrations which have Risk Characterization Ratios > 1. For microorganisms in a STP and for soil living organisms there is no risk to be expected.

Table 2.2.3.6.c: PEC/PNEC ratios for surface water

Exposure scenario	Species/endpoint	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
Rain-water discharge (50 mm) into surface water (separate systems)	Aquatic community	0.044	0.004	**11**
Rain-water discharge (50 mm) into surface water via STP (combined systems)	Aquatic community	0.034	0.004	**8.5**

Table 2.2.3.6.d: PEC/PNEC ratios for sediment

Exposure scenario	Species/end-point	PEC (µg/kg)	PNEC (µg/kg)	PEC/PNEC
Rain-water discharge (50 mm) into sediment (separate systems)	Sediment (EPM)	4.44	0.4	**11.1**
Rain-water discharge (50 mm) into sediment (combined systems)	Sediment (EPM)	3.47	0.4	**8.7**

Table 2.2.3.6.e: PEC/PNEC ratios for the STP compartment

Exposure scenario	Species/endpoint	PEC (µg/L)	PNEC (µg/L)	PEC/PNEC
Rain water discharge into STP	Activated sludge	0.346	100 000	**0.00000346**

Table 2.2.3.6.f: PEC/PNEC ratios for the terrestrial compartment

Exposure scenario	Species/endpoint	PEC (µg/kg wet soil)	PNEC (µg/kg ww)	PEC/PNEC
Soil after application of municipal sewage sludge	Terrestrial organisms (EPM)	0.242	0.33	**0.73**

Mosquito control in septic tanks

For this use, there is no exposure of surface water and sediment. There is a risk shown, however, for the terrestrial communities of the leaching field and a certain risk for contamination of groundwater with the metabolite CPU.

Table 2.2.3.5.g: PEC/PNEC ratios for the terrestrial compartment

Exposure scenario	Species/endpoint	PEC (µg/kg wet soil)	PNEC (µg/kg ww)	PEC/PNEC
Soil within the confinements of the leaching field	Terrestrial organisms (EPM)	9.08	0.33	**27.5**

Degradation of the active substance in soil systems leads to the formation of two metabolites, DFBA and CPU. Due to the fact that CPU has a considerably longer half life than the parent substance (19.7 d compared to 3.5 d at 20˚C), FOCUS groundwater calculations were run for diflubenzuron and for the metabolite CPU. For diflubenzuron, FOCUS modelling showed no exceeding of the groundwater trigger value of 0.1 µg/l. For CPU, however, the trigger value was exceeded slightly in two of 9 model locations.

Table 2.2.3.6.g: FOCUS PEARL groundwater assessment: Results for applications in septic tanks for mosquito control

Location	80th percentile concentration of DFB [µg/L] at 1 m depth	80th percentile concentration of CPU [µg/L] at 1 m depth
Châteaudun	0	0.001453
Hamburg	0	0.065626
Jokioinen	0	0.091017
Kremsműnster	0	0.090341
Okehampton	0	0.16553
Piacenza	0	0.187806
Porto	0	0
Sevilla	0	0.000001
Thiva	0	0.000168

Fly control in poultry farming

This use is limited to poultry farming in such housing which has dry processing of the manure. This is basically the so called deep pit, high-rise caging.

The use in poultry farming shows a risk to soil, if the manure is directly applied to the field. For a safe use, the manure has to undergo composting for about 40 days before it can be used as a fertilizer on agricultural soils.

A PEC for groundwater has not been calculated, as that is already covered by the septic tank scenario, which is more worst-case with respect to soil.

Table 2.2.3.6.h: PEC/PNEC ratios for the terrestrial compartment.

Exposure scenario	Species/endpoint	PIECars-N* (µg/kg wet soil)	PNEC (µg/kg ww)	PEC/PNEC
Scenario 1: composting with "hot phase"	Terrestrial organisms (EPM)	0.016	0.33	**0.047**
Scenario 2: composting without	Terrestrial organisms (EPM)	0.09	0.33	**0.29**

"hot phase"				
Scenario 3: no composting	Terrestrial organisms (EPM)	3.6	0.33	**11**

*The PIECars-N is the concentration of the active substance in soil based on the nitrogen immission standard for arable land. It corresponds to a PEC.

The PIECs for grassland and the resulting PEC/PNEC ratios were not calculated as dry manure is usually not applied to grassland.

Table 2.2.3.6.i: PECs after one year

PEC after 1 year scenario 1	**3.5^{-11} µg/kg wet soil**
PEC after 1 year scenario 2	**2.1^{-10} µg/kg wet soil**

Accumulation over more than a year does not seem to be relevant.

Metabolites

The risk for the metabolites CPU and DFBA is principally covered by the PEC/PNEC ratios of the parent, due to the generally higher toxicity of DFB. However, the PEC/PNEC ratios for CPU on the basis of the earthworm test were calculated below. As a worst case scenario, the same PECs were used as for the parent (i.e. transformation factor DFB – CPU = 1).

Table 2.2.3.6.j: PEC/PNEC ratios for the metabolite CPU

Exposure scenario	Species/endpoint	PIECars-N (µg/kg wet soil)	PNEC (µg/kg dw)	PEC/PNEC
Scenario 1: composting with "hot phase"	Eisenia foetida	0.016	952	**0.000017**
Scenario 2: composting without "hot phase"	Eisenia foetida	0.09	952	**0.000095**

CPU has a considerably longer half life than the parent substance. Thus, the concentration of CPU in soil was calculated after one year. As a worst case scenario, it was assumed that the transformation factor DFB – CPU was 1. Therefore, the same PIECars-N were used as for the parent substance.

Table 2.2.3.6.k: Metabolite CPU

PEC after 1 year scenario 1	**3.8^{-5} µg/kg wet soil**
PEC after 1 year scenario 2	**2.3^{-4} µg/kg wet soil**

2.2.4. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common

principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

Diflubenzuron is an insecticide intended for the control of mosquito and fly larvae. It is a chitin synthesis inhibitor, which due to its specific mechanisms (inhibition of the deposition in the cuticle) mainly affects insects and other arthropods. The chitin synthesis in other taxonomic groups (e.g. in fungi) does not seem to be affected. The substance takes effect only during hatching and moulting. The old chitin cuticle cannot be shed, because the new cuticle is malformed.

Diflubenzuron is intended to control mosquito larvae in water systems and fly larvae in poultry farming. Originally, use in water storage containers for garden irrigation and use on waste disposal areas were also intended, claiming these were closed systems without environmental exposure. This definition was not accepted by the Member States and the uses were withdrawn. Even the originally intended use in animal houses was narrowed and specified during the evaluation process to use in poultry farms with dry manure processing. This is a realistic scenario in practice in a number of Member States.

Diflubenzuron as manufactured is a white, dusty powder with a faint odor characteristic of aromatic compounds. The solubility of diflubenzuron in water is quite low with the highest solubility of 0.32 mg/l at pH 10 (0.1 mg/l at pH 4 and 0.08 mg/l at pH 7). The vapour pressure is $\leq 1.2 \times 10^{-7}$ Pa at 25°C and the log P_{ow} is 3.89 at pH 3.

The content of diflubenzuron in the technical material is determined by HPLC-UV using simple external calibration or external calibration relative to an internal standard. The contents of diflubenzuron and the relevant metabolites CPU and DFBA in soil are determined by LC-MS/MS, with a LOQ of 0.05 mg/kg for all species. The contents of diflubenzuron and the relevant metabolites CPU and DFBA in surface water are determined by LC-MS/MS with a LOQ of 0.1 µg/l for all species. The LOQ is acceptable for drinking water and the method is accepted for that purpose. However, the LOQ is not sufficiently low for surface water, for which a LOQ of 0.04 µg/l is required based on the long-term NOEC on *Daphnia magna*. One further LC-MS/MS method is available for diflubenzuron (parent) in surface water with a LOQ of 0.04 µg/l which is sufficient. The methods provided for surface water are also acceptable for drinking water.

The representative biocidal product Dimilin GR-2 consists of dry, free flowing, essentially non-dusty and stable granules, and has a diflubenzuron content of 2%.

The data on the active substance and on the insecticide product Dimilin GR-2 have demonstrated sufficient efficacy against mosquitoes and flies for inclusion into Annex I to be recommended. However, specific efficacy data for the use in poultry farms has not been presented. Thus, further efficacy data will be required to support product authorization.

Diflubenzuron shows a high toxicity towards aquatic organisms and repeated exposure to mammals causes haematological effects (increased methaemoglobin and sulfhaemoglobin with consequent erythrocyte degradation, spleen and liver haemosiderosis, liver damage and abnormal blood cell production).

The proposed classification for diflubenzuron is Aquatic Acute 1 and Aquatic Chronic 1; H400, H410 according to the criteria in CLP and N; R50/53 according to the criteria in Directive 67/548/EEC. The Technical Committee on the Classification and Labelling of Dangerous Substances (Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals, JRC Ispra - January 25, 2007) has agreed to classify the substance as N; R50-53 with an M-factor of 100.

The proposed classification for health hazards is STOT RE 2; H373 according to the criteria in CLP and Xn; R48/20/21/22 according to the criteria in Directive 67/548/EEC.

Diflubenzuron oxidises haemoglobin to methaemoglobin. This is seen in most of the studies with diflubenzuron together with formation of sulfhaemoglobin. It has been reported that man and dog are less effective in reducing methaemoglobin than mouse, rabbit, guinea pig and monkey. It can therefore be assumed that man and dog are the most sensitive species. The increased formation of methaemoglobin and sulfhaemoglobin seems to cause an increased turnover of erythrocytes and production of blood cells outside the bone marrow. The increased turnover of erythrocytes causes an increased accumulation of iron. Increase of spleen and liver weights and haemosideroses in spleen and liver, as well as damage to the liver has also been observed in different studies. The risk characterisation for human health indicates that diflubenzuron can cause anaemia by increased formation of methaemoglobin and sulfhaemoglobin.

Similar effects as in toxicological studies with diflubenzuron are seen in studies with 4-chloroaniline (PCA), a possible metabolite of diflubenzuron. PCA is a carcinogen, which has a harmonised classification as carcinogenic, Carc. 1B; H350 and Carc. Cat 2; R45 according to CLP Annex VI. Confirmatory data requested under Directive 91/414/EEC, showed that PCA is an in vivo mutagen that can be formed in humans during diflubenzuron metabolism. However, biocide TM I 2012 concluded that the rat data package on diflubenzuron would also cover the risk for humans.

The exposure assessments are based on the documentation submitted for the active substance and the representative biocidal product; the uses taken into account were mosquito control in gully holes and septic tanks, and fly control in poultry farming with dry manure processing. The application is carried out by professionals only. In these scenarios, application of Dimilin GR-2 is not associated with any risk to human health for professionals, provided that gloves, boots, cotton overalls and eye protection are worn.

The calculated exposure levels in the worst case scenarios identified for incidental exposure do not indicate a risk either for bystanders, who are visiting or working in animal premises treated with Dimilin GR-2, or for infants touching the floor treated with Dimilin GR-2. No dietary risk assessment has been carried out. Should an application for product authorisation be made for uses of diflubenzuron-containing products for uses where the product could be reached and consumed by animals used for food production, a dietary risk assessment would need to be conducted.

There was only one use scenario (in poultry farming) where no risks to environmental compartments were found. Use in gully holes resulted in risk for surface water and sediment; use in septic tanks resulted in risk for soil. Risk mitigation measures could not be applied. Before products for such uses can be authorized, it has to be shown that no risk for the environment is to be expected.

For use as fly control in poultry farming, risk mitigation measures are needed: manure has to undergo composting before it can be applied to arable land.

It is proposed that diflubenzuron shall be included in Annex I of Directive 98/8/EC with the restrictive conditions mentioned under section 3.2.

3.2. Decision regarding Inclusion in Annex I

Diflubenzuron shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type **18** (insecticides, acaricides and products to control other arthropods), subject to the following specific provisions:

- The active substance diflubenzuron shall have a minimum purity of 960 g/kg

- The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use, use by non-professionals, and exposure of livestock were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI of the Biocidal Products Directive (98/8/EC), Member States shall assess exposure to populations and environmental compartments and uses or exposure scenarios that have not been representatively addressed in the risk assessments presented in the CAR. In particular, where relevant, Member States shall assess outdoor use and use by non-professionals.

- For products containing diflubenzuron that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Special considerations need to be given to the *in vivo* genotoxic metabolite PCA.

- Member States shall ensure that authorisations are subject to the following conditions unless it can be demonstrated in the application for product authorisation that the risks can be reduced to an acceptable level:

    (1) Professional users must wear appropriate personal protective equipment;

    (2) Where products are used on manure (e.g. in poultry farming), they can only be used on dry manure. Prior to application on arable land the treated manure must be subject to complete aerobic composting by professionals;

    (3) Products shall not be authorised for use in water systems.

3.3. Elements to be taken into account by Member States when authorising products

Exposure during manufacture of the active substance and formulations has not been considered in this assessment as it is assumed to be within the scope of other legislation on worker safety.

Exposure of non-professional operators has not been considered in this CA report, since the intended use stated for Dimilin GR-2 is professional only. If the intended use will be extended in the future, exposure of non-professional operators must be assessed.

Exposure of livestock and human exposure via food of animal origin has not been considered, as there was no common procedure available for animal exposure assessments and dietary risk assessments of biocides at the time of writing the CAR. Harmonized guidance is expected to become available during 2012. This guidance should be applied at the registration and authorisation of biocidal products containing diflubenzuron, if the product is intended to be used in such way that it could be reached and consumed by animals.

Methods for the determination of residues of diflubenzuron and PCA in food and feeding stuffs of animal origin will be required for uses of products containing diflubenzuron that may lead to residues in food or feed.

The risk assessments performed are based on the use of granules containing 2 % diflubenzuron, and treatment of maximum 1000 m^2 over two hours. For other application rates, new human health risk assessments are needed.

The outer layer of the Dimilin GR-2 granules is supposed to immediately dissolve as it reacts with humidity. However, the secondary exposure of bystanders to Dimilin GR-2 is calculated assuming that some granules are undisolved (they might have ended up at a dry place) so that a child could pick them up in order to represent a worst-case exposure. In case other use areas are relevant, new risk assessments of secondary exposure are needed.

As specific efficacy data for the use in poultry farms has not been presented, such data will be required to support product authorization on Member State level.

Risk to soil organisms has been identified if treated poultry manure is spread directly on arable soils. Obligatory professional composting of the manure before application to soils should be requested. This decreases the concentrations of the active substance to an acceptable level, if the composting is complete, aerobic, and this process is adequately controlled. Uncontrolled storage is not a substitute for professional composting.

A groundwater assessment has not been carried out for the poultry scenario. Risks for groundwater should be excluded before authorizing products on a national level.

In view of the assumptions made during the risk assessment that the manure storage, handling and processing occurs entirely in dry state, product authorization should prohibit uses where the manure or parts of it are processed as slurry and/or are going into a sewage treatment plant, unless it can be demonstrated that risks will be acceptable under such conditions.

When evaluating products containing diflubenzuron, Member States should take into account cumulative exposure from biocidal uses of diflubenzuron (in accordance with Article 10(1) of Directive 98/8/EC) using agreed EU guidance where possible..

Member States should consider requiring a storage stability study for the biocidal product, in which the content of the relevant impurity PCA is assessed during the course of the study using an analytical method validated for that purpose. The outcome of such a study should be taken into account for the risk assessment.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of Diflubenzuron in Annex I to Directive 98/8/EC.

3.5. Updating this Assessment Report

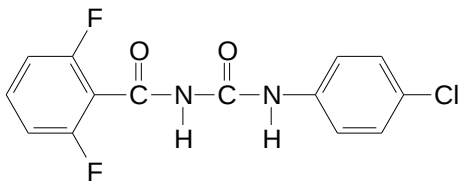
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of Diflubenzuron in Annex I to the Directive.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	diflubenzuron
Product-type	Insecticide (PT 18)

Identity

Chemical name (IUPAC)	1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea
Chemical name (CA)	N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide
CAS No	35367-38-5
EC No	252-529-3
Other substance No.	CIPAC-No: 339
Minimum purity of the active substance as manufactured (g/kg or g/l)	960 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Technical diflubenzuron contains the relevant impurity 4-chloroaniline (PCA) at a maximum of 0.03 g/kg (30 ppm)
Molecular formula	$C_{14}H_9ClF_2N_2O_2$
Molecular mass	310.7 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	227.6 ± 0.3°C (>99.5% purity)
Boiling point (state purity)	257 °C at reduced pressure (40.0 kPa)(99.1% purity)
Temperature of decomposition	Not relevant
Appearance (state purity)	Purified material (99.9% purity) White (Munsell denotation N 9.5/) crystalline odourless solid consisting of very fine needle-like crystals. Technical material (99.1% purity) White (Munsell denotation N 9.5/) dusty powder with a faint odour characteristic of aromatic compounds.
Relative density (state purity)	D_4^{20}=1.569 ± 0.005 (>99.5% purity)
Surface tension	Not applicable as the solubility in water is below 1 mg/l
Vapour pressure (in Pa, state temperature)	≤1.2 x 10^{-7} Pa at 25 °C (>99.5% purity)
Henry's law constant (Pa m^3 mol^{-1})	≤4.7 x 10^{-4} Pa.m^3 mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH 4: 0.1 mg/l (25°C; 99.9% purity) pH 7: 0.08 mg/l (25°C; 99.9% purity) pH 10: 0.32 mg/l (25°C; 99.9% purity) 0.08 mg/l at uncontrolled pH (25°C; 99.9% purity)
Solubility in organic solvents (in g/l or mg/l, state temperature)	At 20°C and 99.9% purity: 0.063 g/l in n-hexane 0.29 g/l in toluene 1.8 g/l in dichloromethane 1.1 g/l in methanol At 20°C and 99.1% purity: 6.98 g/l in acetone 0.48 g/l in ethyl acetate
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable because the active substance as manufactured does not include an organic solvent and the active substance is not formulated in organic solution in the biocidal product
Partition coefficient (log P_{OW}) (state temperature)	pH 3.0: Log P_{ow} =3.89 at 22°C (97.6% purity) The pH dependency has not been assessed. However, as the water solubility is affected at alkaline pH the log P_{ow} is anticipated to be slightly lower at alkaline pH.
Hydrolytic stability (DT_{50}) (state pH and temperature)	See chapter 4 below.
Dissociation constant	
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Abs max in acetonitrile (99.9% purity): 257 nm (ε: 15148) No maxima above 290 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH)	See chapter 4 below

Quantum yield of direct phototransformation in water at Σ > 290 nm	See chapter 4 below
Flammability	Not highly flammable (99.1% purity)
Explosive properties	Not explosive (99.1% purity)

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	H373, (Xn, R48/20/21/22)
with regard to fate and behaviour data	H410 (N, R50/53)
with regard to ecotoxicological data	H410 (N, R50/53)

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	HPLC-UV
Impurities in technical active substance (principle of method)	The relevant impurity PCA is determined in the technical material using HPLC-UV. For the analysis of the remaining impurities see the Confidential Annex.

Analytical methods for residues

Soil (principle of method and LOQ)	diflubenzuron and relevant metabolites CPU and DFBA: LC-MS/MS (LOQ 0.05 mg/kg for all analytes)
Air (principle of method and LOQ)	diflubenzuron: LC-MS/MS (LOQ 0.6 µg/m^3)
Water (principle of method and LOQ)	Surface water: diflubenzuron and relevant metabolites CPU and DFBA: LC-MS/MS (LOQ 0.1 µg/l for all analytes). diflubenzuron: LC-MS/MS (LOQ 0.04 µg/l) Drinking water: The above mentioned methods are accepted also for drinking water
Body fluids and tissues (principle of method and LOQ)	Not required as diflubenzuron is not classified as toxic or highly toxic
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required as the use pattern of diflubenzuron as a biocide will not results in any contact with food or feeding stuffs of plant origin.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	The need for a monitoring method for food/feed of animal origin can only be concluded on after a dietary risk assessment has been conducted. This needs to be addressed when authorising the biocidal products.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Oral absorption 33 %. Diflubenzuron is poorly absorbed from the gastro-intestinal tract and absorption decreased with increasing dose.
Rate and extent of dermal absorption:	Dermal absorption 6 %. Dermal absorption occurred within 1 hour of dosing.
Distribution:	Uniformly distributed
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Excretion almost completely in 24 hours
Toxicologically significant metabolite(s)	Major metabolites; 4-chloroaniline, 4-chloroaniline-2-sulfate, n-(4-chlorophenyl)oxamic acid and 2'-hydroxy-diflubenzuron

Acute toxicity

Rat LD_{50} oral	Rat: > 4640 mg/kg bw/day Mouse: > 4640 mg/kg bw/day
Rat LD_{50} dermal	Rat: > 2000 mg/kg bw/day Rabbit: > 2000 mg/kg bw/day
Rat LC_{50} inhalation	Rat: > 2.5 mg/L/4h (nose-only, dust) Rabbit: >3.7 mg/L/4h (whole body, dust)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Non-sensitiser (Magnussen & Klingman)

Repeated dose toxicity

Species/ target / critical effect	Liver and spleen, increase in methaemoglobin, sulfhaemoglobin and changes in other blood parameters, increased liver and spleen weight and other signs of anaemia like chronic hepatitis, liver haemosiderosis, congestion of the spleen, mild erythroid hyperplasia in boon marrow and Heinz bodies.
Lowest relevant oral NOAEL / LOAEL	$NOAEL_{medium\ term}$ = 2 mg/kg bw/day (1 y dog study) $LOAEL_{acute}$ = 81mg/kg bw/day (28 d rat study) $NOAEL_{long\ term}$ = 1.2 mg/kg bw/day (91 w mouse study)
Lowest relevant dermal NOAEL / LOAEL	NOAEL = 150 mg/kg bw/day (21 d rabbit study)

Lowest relevant inhalation NOAEL / LOAEL	NOAEL = 0.1 mg/L (28 d rat study)

Genotoxicity

Genotoxicity	No genotoxic potential

Carcinogenicity

Species/type of tumour	No carcinogenic potential
lowest dose with tumours	

Reproductive toxicity

Species/ Reproduction target / critical effect	No effect on reproduction or fertility
Lowest relevant reproductive NOAEL / LOAEL	NOAEL ≥ 1000 mg/kg bw/day (rat and rabbit)
Species/Developmental target / critical effect	Treatment-related disturbances of red cell parameters, increased methaemoglobin, liver and spleen weights with associated histopathology including pigmentation, haemosiderosis and red pulp congestion. Parental toxicity, rat (two generation study) LOAEL = 30 mg/kg bw/day (500 ppm) (lowest dose tested)
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Rat and rabbit > 1000 mg/kg bw/day

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No data, no study required
Lowest relevant developmental NOAEL / LOAEL.	

Other toxicological studies

No data, no study required

Medical data

No evidence of adverse effects to workers of manufacturing plants, agricultural worker and consumers

Summary

	Value	Study	Safety factor

Non-professional user	No data		
ADI (acceptable daily intake, external long-term reference dose)	0.012 mg/kg bw/day	91 w mouse	100
AEL-S (Operator Exposure)			
$AEL_{medium-term}$	0.0066 mg/kg bw/day	1 y dog	100
AEL_{acute}	0.13 mg/kg bw/day	28 d rat	200 (from LOAEL)
$AEL_{long-term}$	0.004 mg/kg bw/day	91 week mouse	100
ARfD (acute reference dose)	Does not need to be set		

Acceptable exposure scenarios (including method of calculation)

Professional users	
Production of active substance:	Acceptable exposure
Formulation of biocidal product	Acceptable exposure
Intended uses	The handling of granule formulation by professional users (farmers) using gloves, cotton overall ending above the boots and eye protection is accepted (91 % of AEL) for the following two exposure scenario: Mosquito control in gully-holes and septic tanks. Fly control in animal houses; poultry farming, under gage hens. (Default values for the calculation is taken from TNsG pt 2 p 111 and 198, Professionals using pesticides and Consumer product spraying and dusting, model 2 – max range value)
Secondary exposure	Negligible
Non-professional users	Negligible
Indirect exposure as a result of use	Negligible

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	No degradation at pH 5 or 7. Degradation to CPU and DFBA at pH 9 with DT_{50} =32.5 d (25°C). Major metabolites CPU and DFBA both have DT_{50} of greater than one year at pH 4, 7 and 9 (25°C).
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	DT_{50} = 80 days of sunlight (at 40 °N). Minor route of degradation.
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not relevant.
Aerobic degradation in fresh water water/sediment systems	Water phase DT_{50} 6.1 and 5.3 days for river and pond systems respectively (normalized to 12 °C). Whole system: 10.2 and 7.0 days for river and pond systems respectively (12 °C).
Non-extractable residues	Non-extractable residues in sediment reached 36.4% and 44.4% after 104 days (pond and river system, resp.).
Distribution in water / sediment systems (active substance)	Distribution (max 82% in water at d 0.17. max 24.4 % in sed. at d 1; synopsis from river and pond system).
Distribution in water / sediment systems (metabolites)	CPU: Distribution (max in water 31% at d 8., in sed. 21% at d 30, in whole syst. 48 % at d 16; synopsis from river and pond system). DFBA: Distribution (max in water 13% at d 4., max. sed 3.7% at d 4, in whole syst. 17% at d 4; synopsis from river and pond system).

Route and rate of degradation in soil

Mineralization (aerobic)	39.5-41.2 % after 59 d (20 °C, n=3); 26.3 % after 21 d (24 °C, n=1), labelled in both phenylgroups.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Parent: Geometric mean 7.5 days, range 4.9 to 12.7 days, (4 soils), normalised to 12°C. DT_{90lab} (20°C, aerobic): 8.6-22.2 days Metabolite CPU: Geometric mean 42 days, range 31.9 to 63.7 days, (3 soils), normalised to 12°C. Metabolite DFBA: Geometric mean 12.0 days, range 6.8 to 17.1 days, (3 soils), normalised to 20°C.
	Degradation in the saturated zone: no data

Field studies (state location, range or median with number of measurements)	$DT_{50field}$: Not relevant.
	DT_{90f}: Not relevant
Anaerobic degradation	DT_{50lab} (20°C, anaerobic): 83.6 days (normalized to 12 °C ,1 soil). 6.4 % NER and 2.77 % mineralisation after 90 d; main metabolites DFBA and CPU, labelled in both phenyl groups.
Soil photolysis	35 % NER and 9 % mineralisation after 16 d; main metabolites CPU, labelled in both phenyl groups.
Non-extractable residues	48.3-55 % (after 59 d, n=3); 37.4 % after 21 d (n=1).
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	2,6-difluorobenzoic acid (DFBA) max. 7.1-13.3 % at day 6-13 (n=3), 4-chlorophenylura (CPU) max. 19.2-30.8% at day 13 (n=3).
Soil accumulation and plateau concentration	Not relevant.

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc}	Parent : K_{OC} (mL/g): geometric mean 4609, range 1938 to 6918. Kd: geometric mean 65.2 , range 34.2-97.7 Metabolite CPU: K_{OC} (mL/g): geometric mean 245, range 209 to 291. Kd: geometric mean 3.2 , range 1.2-6.0 Metabolite DFBA: K_{OC} (mL/g): not determined
pH dependence (yes / no) (if yes type of dependence)	No pH dependence.

Fate and behaviour in air

Direct photolysis in air	Not volatile. No data required.
Quantum yield of direct photolysis	not available
Photo-oxidative degradation in air	7.9 hours (with 24 hours day and a [OHrad] of 1.5×10^{-6}), respectively 23.7 hours (with a 12 hours day and a [OHrad] of 0.5×10^{-6}, EPI Suite calculations)
Volatilization	Negligible.

Monitoring data, if available

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Cyprinodon variegatus (sheepshead minnow)	Acute	96 h LC50	>0.13 mg/L
Oncorhynchus mykiss (rainbow trout)	Prolonged	21 day NOEC	0.2 mg/L (the highest concentration tested)
Invertebrates			
Daphnia magna (waterflea)	Acute	48 h, static EC50	2.6 µg/L
Mercenaria mercenaria (Venus clams)	Acute	48h static NOEC	320 µg/L
Daphnia magna (waterflea)	Chronic	21 day NOEC	0.04 µg/L
Mysidopsis bahia	Chronic	28 day NOEC	0.045 µg/L
Algae			
Selenastrum capricornutum	Chronic	72 h EC50	>0.2mg/L
Microorganisms			
Activated sludge	3 hours	Respiration inhibition	NOEC: 1000 mg/L
Aquatic plants			
Lemna gibba	Acute	14-day EC_{50}	>0.190 mg/L
Community			
A littoral enclosure study and a literature review were submitted by the notifier in order to refine the aquatic risk assessment. The littoral enclosure study had a number of shortcomings, however. Several important groups of organisms were lacking, or were only present in too low numbers, or were too variable to allow for a meaningful assessment. Additionally, all given concentrations were nominal concentrations, not measured concentrations. Therefore, a PNEC could not be derived.			

Metabolites

Species	Time-scale	Endpoint	Toxicity
4-Chlorphenylurea (CPU)			
Brachydanio rerio (Zebra fish)	Acute	96 h LC50	70 mg/L
Daphnia magna (waterflea)	Acute	48 h, static, EC50	116 mg/L
Selenastrum capricornutum	Chronic	72 h EC50	Biomass: 30 mg/L Growth rate: 95 mg/L
2,6-difluorobenzoic acid (DFBA)			
Brachydanio rerio (Zebra fish)	Acute	96 h, static LC50	>100 mg/L
Daphnia magna (waterflea)	Acute	48 h, static, EC50	>60 mg/L
Selenastrum capricornutum	Chronic	72 h EC50	>100 mg/L (biomass & growth)

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia foetida*.	LC_{50corr} technical >398 mg/kg ww soil (the highest concentration tested). Endpoint has been normalized to standard organic matter content in test soil. LC_{50} metabolite CPU 952 mg/kg ww soil LC_{50} metabolite DFBA >1390 mg/kg ww soil Endpoints not normalized due to low log Pow (1.14 and -0.02, respectively).
Reproductive toxicity to *Eisenia foetida*.	Not determined

Effects on soil micro-organisms

Nitrogen mineralization	Short term effects on nitrate formation, but effects disappeared after > 1 months at 1.26 mg/kg dw
Carbon mineralization	< 25 % effect at 1.26 mg/kg dw

Effects on terrestrial vertebrates

Acute toxicity to mammals	Rat and mouse LD50: >4640 mg/kg
Acute toxicity to birds	Mallard duck, Bobwhite quail: LD50: >5000 mg/kg bw
Dietary toxicity to birds	Bobwhite quail: LD50: >1206 mg/kg bw/day
Reproductive toxicity to birds	Bobwhite quail NOEC =42.7 mg/kg bw/day

Effects on honeybees

Acute oral toxicity	Literature data > 25 µg/bee
Acute contact toxicity	Literature data > 30 µg/bee

Field

From the considerable amount of field data it is apparent that that honey bee larvae are considerably more sensitive than adults. However, given the use patterns of diflubenzuron and type of environment where applications will be made it is unlikely that honey bees will be exposed.

Effects on other beneficial arthropods

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
Laboratory tests					
Aphidius rhopalosiphi	(adult)	Dimilin WG-80	0.144	survival and fecundity	No significant effect on survival, no interpretation of effects on fecundity could be made
Typhlodromus pyri	Proto nymph	Dimilin WG-80	0.144	survival and fecundity	No significant effect
Aleochara bilineata	Life cycle	Dimilin WG-80	0.180	Adult survival and ability to produce eggs	Not affected. Fecundity test not considered valid since only 10 % emerged in controls

Extended laboratory studies and semi-field tests					
Episyrphus balteus	Life-cycle	Dimilin WG-80	0.120	Pre-imaginal mortality	97.5 % Fecundity test not considered valid.
Coccinella septempunctata	Life-cycle	Dimilin WG-80	0.040-0.320 g	LR50 NOEC fecundity	168 g a.s./ha (i.e. 210 g product/ha), 95 % CI 48.3-256 g a.s./ha (i.e 60-318 g product/ha). 100 g product/ha (i.e. 80 g a.s./ha)
Chrysoperla carnea		Dimilin WG-80	0.0004-0.0064	LR50	nominally 1.3 g a.s./ha (i.e. 1.6 g product/ha), 95 % CI 0.9-1.7 g a.s./ha (i.e. 1.2-2.1 g product/ha.)

Bioconcentration

Bioconcentration factor (BCF)	320 (± 70) in bluegill sunfish. Although the study was not considered fully valid it indicated a low potential for bioconcentration
Depuration time (DT_{50})	0.60 (± 0.09) days
(DT_{90})	2.0 (± 0.31) days
Level of metabolites (%) in organisms accounting for > 10 % of residues	The major metabolite present was identified by mass spectrometry as 2,6-difluorobenzamide (12%, 16% and 11% in whole fish, fillet and viscera, respectively).

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Intended uses evaluated for the representative biocidal product Dimilin GR-2

Application type	User category	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
Manual (broad cast) made directly to water surface	Professional PCO or farmer	Repeated as necessary; maximum number of applications is 4 per mosquito season. Application rate dependent on type of water: - High organic polluted water 1 g a.s./1 m³ (equivalent to 1 mg a.s./L) - Dirty water 1 g a.s./4 m³ (equivalent to 0.25 mg a.s./L) - Clear water 1 g a.s./8 m³ (equivalent to 0.125 mg a.s./L) Minimum interval of 1 month.	None.	Dimilin GR-2 is a granule formulation (containing 20 g a.s./kg), used for the following purposes: 1) Mosquito control Mosquito larvae in water systems (gully-holes and septic tanks in urban, suburban and rural areas)	South-Europe: April – September Central & North Europe: June - September
Manual (broad cast) made directly to horizontal surfaces (i.e. not applied to walls)	Professional (farmer) only	Repeated as necessary. Maximum number of applications is 3 per fly season. Rate: 0.5 a.s./m² In poultry farming the following intervals generally are appropriate: Poultry houses: 4-5 weeks	None.	2) Fly control Fly larvae indoor use: in dry manure in poultry farms (limited to dry manure heaps under caged hens; minimum dry matter content 30% of ww. Note: any manure which is not incinerated should be composted for about 40 days prior to use as fertilizer.)	South-Europe: April – September Central & North Europe: June - September

Risks have been identified for the grayed out use and it is not considered supported by the available data (i.e. it has to be further refined at MS-level)

Appendix III: List of studies

Data protection should be claimed by the Applicant in accordance with Article 12.1(c) (i) or (ii) of Council Directive 98/8/EC and this should be marked Y(i) or Y(ii). However in the provided reference list data protection claims are only marked Y. Hereby, the applicant has been informed that an amended list of references might be required for the final CAR. However in the provided reference list data protection claims are only marked Y. It should also be noted that the data protection column and owner column have not been addressed for some of the studies and this also need to be amended.

These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Abbreviation	**Data owner**
CHEM	Chemtura Europe Limited

Section No.	**Author(s)**	**Year**	**Title** **Company, Report No** **GLP or GEP status** **Published or not**	**Data protection claimed** **Y/N**	**Owner**
A2.6/01	White, C.K.	1997	Final Report - Description of the production process for Dimilin Report Uniroyal Chemical Co. Inc., Middlebury, U.S.A. 96288 - DI – 11253 Not GLP Not published (**Confidential**)	Y	CHEM
A2.7/01 A2.8/01	Riggs, A.S.	2007	Preliminary analysis of diflubenzuron technical Chemtura Canada Co./Cie, Ontario, Canada. Study No. GRL-12508 Chemtura corporation study DI-011828 GLP Not published (**Confidential**)	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A.2.8/02	Tutty, D.G.	2007	Explanation of the certified limits if diflubenzuron technical Chemtura Canada Co./Cie, Ontario, Canada. Study No. GRL-12498 Chemtura corporation study DI-011829 Not GLP Not published (**Confidential**)	Y	CHEM
A2.7/02 A2.8/03	Tutty, D. G.	2010	Certified limits of diflubenzuron technical, Final Report Chemtura Canada Co./Cie Guelph Technology Centre PO Box 1120, 120 Huron Street Guelph, Ontario Canada N1H 6N3 Test Facility Study No.: GRL-12830 Not GLP, Not published (**Confidential**)	Y	CHEM
A3.1/01	THUS, J.L.G., MARS, J.J. VAN DE, HARBERS, G.J.	1995	DETERMINATION OF THE UV-VIS SPECTRA AND MELTING POINT OF DIFLUBENZURON REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56834/07/1995 - DI – 9321 GLP NOT PUBLISHED	Y	CHEM
A3.1/02	RIGGS, A.S.	1999	THE BOILING POINT OF DIFLUBENZURON TECHNICAL REPORT UNIROYAL CHEMICAL RESEARCH LABORATORY ONTARIO, CANADA NO.GRL-FR-11576 REP-179 - DI – 11496 GLP NOT PUBLISHED	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A3.1/03	HENGELMOLEN, R.	2000	RELATIVE DENSITY OF ANALYTICAL GRADE DIFLUBENZURON REPORT UNIROYAL CHEMICAL EUROPE B.V., THE NETHERLANDS NO.910/03/2000 - DI – 11597 GLP NOT PUBLISHED	Y	CHEM
A3.2/01	HARTEVELD, J.L.N.	1988	THE VAPOUR PRESSURE OF DIFLUBENZURON REPORT DUPHAR B.V., THE NETHERLANDS NO.56630/258/1988 - DI – 7081 GLP NOT PUBLISHED	Y	CHEM
A3.3/01	RIGGS, A.S.	2000	THE COLOUR, PHYSICAL STATE AND ODOUR OF PURIFIED DIFLUBENZURON REPORT UNIROYAL RESEARCH LABORATORY, ONTARIO, CANADA GRL-FR-10981 - DI – 11599 GLP NOT PUBLISHED	Y	CHEM
A3.3/02	FRIEDLANDER, B.T.	1999a	THE COLOR OF DIFLUBENZURON TECHNICAL REPORT UNIROYAL CHEMICAL RESEARCH LABORATORY ONTARIO, CANADA NO.GRL-11519 - DI – 11385 GLP NOT PUBLISHED	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A3.3/03	FRIEDLANDER, B.T.	1998	FINAL REPORT - THE PHYSICAL STATE OF DIFLUBENZURON TECHNICAL REPORT UNIROYAL RESEARCH LABORATORY, ONTARIO, CANADA GRL-FR-11299 - DI – 11260 GLP NOT PUBLISHED	Y	CHEM
A3.3/04	FRIEDLANDER, B.T.	1999b	THE ODOR OF DIFLUBENZURON TECHNICAL REPORT UNIROYAL CHEMICAL RESEARCH LABORATORY ONTARIO, CANADA NO.GRL-11520 DI – 11389 GLP NOT PUBLISHED	Y	CHEM
A3.4/01 A3.4/02	BLASZCZYNSKI, E.	2004	TITLE IS CONFIDENTIAL (SEE CONFIDENTIAL ATTACHMENT). REPORT CHEMMPTON CORPORATION STUDY N0. 2003-014. - DI – 11729 GLP NOT PUBLISHED (**CONFIDENTIAL**)	Y	CHEM
A3.5/01	BALDER, B.G., FEENSTRA-BIELDERS, G., POUWELSE, A.V.	1989	SOLUBILITY OF DIFLUBENZURON IN WATER AT 298 K REPORT DUPHAR B.V., THE NETHERLANDS NO.56630/85/1989 - DI – 7233 GLP NOT PUBLISHED	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A3.5/02	KEMPEN, A. VAN, FEENSTRA-BIELDERS, G., THUS, J.	1995	SOLUBILITY OF DIFLUBENZURON AT PH 4, 7 AND 10 REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56830/46/1994 - DI – 9167 GLP NOT PUBLISHED	Y	CHEM
A3.6/01	YU, W.S.	1999a	DETERMINATION OF THE DISSOCIATION CONSTANT OF DIFLUBENZURON REPORT UNIROYAL CHEMICAL RESEARCH LABORATORY ONTARIO, CANADA NO.GRL-11521 DI – 11387 GLP NOT PUBLISHED	Y	CHEM
A3.7/01	KEMPEN, A. VAN, FEENSTRA-BIELDERS, G.	1995	SOLUBILITY OF DIFLUBENZURON IN ORGANIC SOLVENTS REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56830/52/1994 - DI – 9168 GLP NOT PUBLISHED	Y	CHEM
A3.7/02	YU, W.S.	1999b	DETERMINATION OF SOLUBILITY OF DIFLUBENZURON TECHNICAL IN ACETONE AND IN ETHYL ACETATE REPORT UNIROYAL CHEMICAL RESEARCH LABORATORY ONTARIO, CANADA NO.GRL-FR-11577 DI – 11489 GLP NOT PUBLISHED	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A3.9/01	THUS, J.L.G.	1988	DETERMINATION BY HPLC OF THE LOG P VALUE OF DIFLUBENZURON AND ITS PRIMARY METABOLITES REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/36/1988 - DI – 7016 NO GLP NOT PUBLISHED	Y	CHEM
A3.11/01	FLACK,I.	1999	DIFLUBENZURON TECHNICAL - PHYSICOCHEMICAL PROPERTIES REPORT HUNTINGDON LIFE SCIENCES LTD., ENGLAND NO.URO 014/994683 - DI – 11516 GLP NOT PUBLISHED	Y	CHEM
A3.15/01	FLACK, I.	1999	DIFLUBENZURON TECHNICAL - PHYSICOCHEMICAL PROPERTIES REPORT HUNTINGDON LIFE SCIENCES LTD., ENGLAND NO.URO 014/994683 - DI – 11516 GLP NOT PUBLISHED	Y	CHEM
A3.16/01	FLACK, I.	1999	DIFLUBENZURON TECHNICAL - PHYSICOCHEMICAL PROPERTIES REPORT HUNTINGDON LIFE SCIENCES LTD., ENGLAND NO.URO 014/994683 - DI – 11516 GLP NOT PUBLISHED	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A4.1/01	Zeijl, E. van	2001	Validation of the analytical method for the determination of diflubenzuron and its impurities in diflubenzuron technical and Dimilin WG-80 by High Performance Liquid Chromatography and external standardization. Report Uniroyal Chemical Europe B.V., The Netherlands No. C.303.10.027, DI – 11647. GLP, not published.	Y	CHEM
A4.1/02	Zeijl, E. van	2002	Validation of the analytical method for the determination of diflubenzuron and its impurities in diflubenzuron technical and Dimilin WG-80 by High Performance Liquid Chromatography and external standardization (Amendment 1). Report Uniroyal Chemical Europe B.V., The Netherlands No. C.303.10.027, DI – 11647. GLP, Not published.	Y	CHEM
A4.1/04	Goebel, N.E.	2007	Determination of diflubenzuron in technical and formulated materials by high performance liquid chromatography with internal standardization Method No. GRL-GM-1066 GLP, not published.	Y	CHEM
A4.1/05	Zeijl, E. van	2003	Liquid-chromatographic determination of XXX in diflubenzuron technical grade Report Crompton Europe B.V., The Netherlands - DI – 11740 GLP, Not published (**Confidential**)	Y	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A4.1/06	Riggs, A.S.	2003	Analytical method: determination of trace organic impurities in diflubenzuron technical material using high performance liquid chromatography. Report Crompton Co. Research Laboratories, Ontario, Canada No. GRL-GM-1188. GLP, Not published (**Confidential**)	Y	CHEM
A4.2(a)/01	Faltynski, K.H.	2003a	Development and validation of an analytical method for the determination of diflubenzuron, 4-chlorophenylura and 2,6-difluorobenzoic acid in soil.. Report EN-CAS Analytical Laboratories, U.S.A. No. 02-0040 (Crompton Study No. 2002-059), DI – 11741. GLP, not published.	N	CHEM
A4.2(b)/01	Bacher, R.	2006	Validation of an analytical confirmatory method for the determination of diflubenzuron in air. Report PTRL Europe GmbH, Germany, No. B 1000 G (Chemtura 2006-001), DI – 11817. GLP, not published.	Y	CHEM
A4.2(c)/01	Faltynski, K.H.	2003b	Development and validation of analytical method for the determination of diflubenzuron, 4-chlorophenylurea and 2,6-difluorobenzoic acid in pond water. Report EN-CAS analytical laboratories, U.S.A. No. 03-0005 (Crompton study No. 2003-038), DI – 11737. GLP, not published.	N	CHEM
A4.2(c)/02	Deutsch, R.	2003	AGVISE Water Characterization Report AGVISE Lab No 03-0024	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A4.2(c)/03	Wolf, S.	2009	DIFLUBENZURON Validation of a Residue Analytical Method for the Determination of Diflubenzuron in Surface Water Harlan Laboratories Ltd. Zelgliweg 1 4452 Itingen / Switzerland Study Identification: Harlan Laboratories Study C29546 GLP, not published.	Y	CHEM
A6.1.1 (01)	ELDIK,A.VAN .	1973	ACUTE TOXICITY STUDIES WITH DU 112307 IN MICE AND RATS REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/14/1973 DI - 2207 GLP: NO Published: NO	N	CHEM
A6.1.1 (02)	KOOPMAN,T.S. M.	1984	ACUTE ORAL TOXICITY STUDY WITH DIFLUBENZURON VC-90 IN RATS REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/30/1984 DI - 4959 GLP: YES Published: NO	N	CHEM
A6.1.1 (03)	KOOPMAN,T.S. M.	1977	ACUTE ORAL TOXICITY STUDY WITH DU 112307 TECHNICAL IN MICE REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/04/1977 DI - 2203 GLP: NO Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.1.1 (04)	KOOPMAN,T.S. M.	1986	ACUTE ORAL TOXICITY STUDY WITH DIFLUBENZURON VC-90% IN MICE REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/39/1986 DI - 5708 GLP: YES Published: NO	N	CHEM
A6.1.2 (01)	KEET,C.M.J.F.	1976	ACUTE TOXICITY IN RATS OF DU 112307 TECHNICAL AFTER DERMAL APPLICATION REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/02/1976 DI - 2227 GLP: NO Published: NO	N	CHEM
A6.1.2 (02)	KOOPMAN,T.S. M.	1977	ACUTE DERMAL TOXICITY STUDY WITH DU 112307 TECHNICAL IN RATS REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/07/1977 DI - 2226 GLP: NO Published: NO	N	CHEM
A6.1.2 (03)	KOOPMAN,T.S. M.	1984	ACUTE DERMAL TOXICITY STUDY WITH DIFLUBENZURON VC-90 IN RATS REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/31/1984 DI - 4958 GLP: YES Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.1.2 (04)	DAVIES,R.E., HALLIDAY,J.C.	1974	ACUTE PERCUTANEOUS TOXICITY TO RABBITS OF DU 112307 TECHNICAL REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.2171/D175/73 DI - 2229 GLP: NO Published: NO	N	CHEM
A6.1.3 (01)	BERCZY,Z.S., COBB,L.M., CHERRY,C.P.	1973	ACUTE INHALATION TOXICITY TO THE RAT OF DU 112307 TECHNICAL GRADE POWDER REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR74/73849 DI - 3513 GLP: NO Published: NO	N	CHEM
A6.1.3 (02)	GREENOUGH,R. JJ., MCDONALD,P.	1986	DIFLUBENZURON VC 90 ACUTE INHALATION TOXICITY STUDY IN RATS (LIMIT TEST) REPORT INVERESK RESEARCH INTERNATIONAL, SCOTLAND NO.56645/41/1986 DI - 5710 GLP: YES Published: NO	N	CHEM
A6.1.3 (03)	BERCZY,Z.S., COBB,L.M., STREET,A.E. et al.	1975	ACUTE INHALATION TOXICITY TO THE RABBIT OF DU 112307 TECHNICAL GRADE POWDER REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR198/74988 DI - 2360 GLP: NO Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.1.4 (01)	TAYLOR,R.E.	1973	PRIMARY SKIN IRRITATION STUDY TH-6040 TECHNICAL (ALBINO RABBIT) REPORT HARRIS LABORATORIES, U.S.A. DI - 2232 GLP: NO Published: NO	N	CHEM
A6.1.4 (02)	KOOPMAN,T.S. M.	1984	PRIMARY IRRITATION OF DIFLUBENZURON VC-90 TO THE RABBIT SKIN REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/44/1984 DI - 4961 GLP: YES Published: NO	N	CHEM
A6.1.4 (03)	DAVIES,R.E., LIGGETT,M.P.	1973	IRRITANT EFFECTS OF DU 112307 TECHNICAL ON RABBIT EYE MUCOSA REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.2170/176D/73 DI - 2367 GLP: NO Published: NO	N	CHEM
A6.1.4 (04)	KOOPMAN,T.S. M.	1984	PRIMARY IRRITATION OF DIFLUBENZURON VC-90 TO THE RABBIT EYE REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/29/1984 DI - 4960 GLP: YES Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.1.5 (01)	KYNOCH,S.R., SMITH,P.A.	1986	DELAYED CONTACT HYPERSENSITIVITY IN THE GUINEA-PIG WITH DIFLUBENZURON VC-90 (DUPHAR REFERENCE NO. 56645/61/86) REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.86558D/ PDR 432SS DI - 5713 GLP: NO Published: NO	N	CHEM
A6.1.5 (02)	PRINSEN,M.K.	1992	SENSITIZATION STUDY WITH DIFLUBENZURON TECHNICAL IN GUINEA PIGS REPORT TNO, THE NETHERLANDS NO.56645/26/1992 DI - 8423 GLP: YES Published: NO	N	CHEM
A6.2 (01)	DUNSIRE,J.P., CAMERON,B.D., SPEIRS,G.C.	1990	THE DISPOSITION OF [14C]DIFLUBENZURON IN THE RAT (STUDY PERFORMED TO JAPANESE GUIDELINES) REPORT INVERESK RESEARCH INTERNATIONAL, SCOTLAND NO.56654/13/1990 DI - 7910 GLP: YES Published: NO	N	CHEM
A6.2 (02)	CAMERON,B.D., HENDERSON,A., MCGUIRE,G.M.	1990	THE METABOLISM OF [14]DIFLUBENZURON IN THE RAT: PROFILING OF RADIOACTIVITY IN URINE, FAECES AND BILE REPORT INVERESK RESEARCH INTERNATIONAL, SCOTLAND NO.56629/64/1990 DI - 7910 GLP: YES Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.2 (03)	WANG,R, McMANUS,J.P., GAY,M.H.	2000	METABOLISM OF [U-14C-ANILINO]-DIFLUBENZURON BY MALE FISHER RATS REPORT UNIROYAL CHEMICAL COMPANY, INC., MIDDLEBURY, USA. REPORT NO.98246. DI - 11636 GLP: YES Published: NO	Y	CHEM
A6.2 (04)	ANDRE,J.C.	1996	DERMAL ABSORPTION OF 14C-DIFLUBENZURON BY MALE SPRAGUE DAWLEY RATS GLP: YES Published: NO	Y	CHEM
A6.3.1 (01)	PALMER, A.K., ALLEN, P.A., STREET, A.E.	1977	PRELIMINARY ASSESSMENT OF THE EFFECT OF DU 112307 ON THE RAT REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR243/77208 DI - 4161 GLP: NO Published: NO	N	CHEM
A6.3.1 (02)	HUNTER,B., JORDAN,J., HEYWOOD,R. et al .	1979	DU 112307 TOXICITY TO RATS IN DIETARY ADMINISTRATION FOR NINE WEEKS FOLLOWED BY A FOUR-WEEK WITHDRAWAL PERIOD REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR248/77883 DI - 3517 GLP: NO Published: NO	N	CHEM

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A6.3.1 (03)	HUNTER,B., BATHAM,P., STREET,A.E. et al .	1974	DU 112307 PRELIMINARY ASSESSMENT OF THE TOXICITY TO MALE MICE IN DIETARY ADMINISTRATION FOR 6 WEEKS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR174/74199 DI - 3523 GLP: NO Published: NO	N	CHEM
A6.3.1 (04)	COLLEY,J.C., BATHAM,P., HEYWOOD,R. et al .	1981	THE EFFECTS OF DIETARY ADMINISTRATION OF DIFLUBENZURON TO MALE AND FEMALE HC/CFLP MICE FOR 14 WEEKS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR294/80185 DI - 4155 GLP: NO Published: NO	N	CHEM
A6.3.2 (01)	GOLDENTHAL,E .I.	1996	21-DAY DERMAL TOXICITY STUDY IN RATS REPORT MPI RESEARCH, MATTAWAN, U.S.A., NO.399-186 DI - 9429 GLP: YES Published: NO	Y	CHEM
A6.3.2 (02)	DAVIES, R.E., HALLIDAY, J.C., STREET, A.E.	1975	EFFECT OF REPEATED APPLICATIONS OF DU 112307 TO THE SKIN OF RABBITS FOR THREE WEEKS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR146/73845 DI - 2217 GLP: NO Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.3.2 (03)	DAVIES,R.E., ELLIOT,P.H., STREET,A.E., HEYWOOD,R., PRENTICE, D.E.	1975	EFFECT OF REPEATED APPLICATIONS OF DU 112307 TO THE SKIN OF RABBITS FOR THREE WEEKS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR200/74851 DI - 2216 GLP: NO Published: NO	N	CHEM
A6.3.3 (01)	BERCZY,Z.S., COBB,L.M., STREET,A.E.	1975	SUBACUTE INHALATION TOXICITY TO THE RAT OF DU 112307 INSECTICIDE POWDER (TECHNICAL) (EVALUATION OF METHAEMOGLOBINAEMIA) REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR197/741013 DI - 2359 GLP: NO Published: NO	N	CHEM
A6.3.3 (02)	NEWTON,P.E.	1999	A 4-WEEK INHALATION TOXICITY STUDY OF DIMILIN TECHNICAL IN RATS REPORT MPI RESEARCH INC. , U.S.A. NO.399-205 DI - 11497 GLP: YES Published: NO	Y	CHEM
A6.3.3 (03)	BERCZY,Z.S., COBB,L.M., STREET,A.E. et al.	1975	SUBACUTE INHALATION TOXICITY TO THE RABBIT OF DU 112307 TECHNICAL GRADE POWDER REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR199/7551 DI - 2357 GLP: NO Published: NO	N	CHEM

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A6.4.1(01)	KEMP,A., HEIJDEN,C.A.VAN DER, ELDIK,A.VAN .	1973	DIETARY ADMINISTRATION OF DU 112307 TO MALE AND FEMALE RATS FOR THREE MONTHS REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/13A/1973 DI -2376 GLP: NO Published: NO	N	CHEM
A6.4.1(01)	KEMP, A., HEIJDEN, A.C.VAN DER, ELDIK, A.VAN (	1973	APPENDIX III TO REPORT NO.56645/13A/1973 INDIVIDUAL DATA: DIETARY ADMINISTRATION OF DU 112307 TO MALE AND FEMALE RATS FOR 3 MONTHS REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/13B/1973 DI - 2376 GLP: NO Published: NO	N	CHEM
A6.4.1(01)	OFFRINGA,O.R.	1977	ADDENDUM REPORT TO THE CHRONIC STUDIES WITH DU 112307 A. DIETARY ADM. TO RATS FOR 104 WEEKS B. DIETARY ADM. TO MICE FOR 80 WEEKS REPORT PHILIPS-DUPHAR B.V., THE NETHERLANDS NO.56645/16/1977 DI - 3528 GLP: NO Published: NO	N	CHEM
A6.4.1 (02)	BURDOCK,G.A., SEROTA,D.G., PURVIS,D. et al .	1980	SUBCHRONIC DIETARY TOXICITY STUDY IN RATS-DIFLUBENZURON REPORT HAZLETON LABORATORIES AMERICA INC., U.S.A. DI - 2168 GLP: YES Published: NO	N	CHEM

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A6.4.1 (02)	GOODMAN,D.G.	1980	HISTOPATHOLOGIC EVALUATION OF RATS ADMINISTERED DIFLUBENZURON IN THE DIET REPORT CLEMENT ASSOCIATES INC., WASHINGTON, U.S.A. DI - 4279 GLP: YES Published: NO	N	CHEM
A6.4.1 (03)	BURDOCK,G.A., SEROTA,D.G., ALSAKER,R.A. et al .	1980	NINETY-DAY SUBCHRONIC TOXICITY STUDY IN MICE - DIFLUBENZURON TECHNICAL REPORT HAZLETON LABORATORIES AMERICA INC., U.S.A. DI - 2212 GLP: YES Published: NO	N	CHEM
A6.4.1 (03)	GOODMAN,D.G.	1980	HISTOPATHOLOGIC EVALUATION OF MICE ADMINISTERED DIFLUBENZURON IN THE DIET REPORT HAZLETON LABORATORIES AMERICA INC., U.S.A. DI - 3522 GLP: YES Published: NO	N	CHEM
A6.4.1 (04)	VERSENDAAL,R .G.VAN, KOSTER,H., KEET,C.M.J.F.	1983	ORAL (CAPSULE) 6-WEEKS DOSE-RANGE-FINDING STUDY WITH DIFLUBENZURON IN MALE AND FEMALE BEAGLE DOGS REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/01/1983 DI - 987 GLP: NO Published: NO	N	CHEM

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A6.4.1 (05)	CHESTERMAN,H., HEYWOOD,R., BARKER,M.H. et al .	1974	DU 112307 TOXICITY IN REPEATED DIETARY ADMINISTRATION TO BEAGLE DOGS (REPEATED ADMINISTRATION FOR 13 WEEKS) REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR169/74157 DI - 2375 GLP: NO Published: NO	N	CHEM
A6.4.1 (06)	GREENOUGH,R. J., GOBURDHUN,R., HUDSON,R. et al .	1985	DIFLUBENZURON. 52 WEEK ORAL TOXICITY STUDY IN DOGS. (VOLUME 1 AND 2) REPORT INVERESK RESEARCH INTERNATIONAL, SCOTLAND NO.56645/32/1985 DI - 4852 GLP: YES Published: NO	N	CHEM
A6.5 (01)	HUNTER,B., COLLEY,J., STREET,A.E. et al .	1976	EFFECTS OF DU 112307 IN DIETARY ADMINISTRATION TO RATS FOR 104 WEEKS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR171/75945 DI - 4037 GLP: NO Published: NO	N	CHEM
A6.5 (01)	COLLEY,J., OFFER,J.M.	1977	EFFECTS OF DU 112307 IN DIETARY ADMINISTRATION TO RATS FOR 104 WEEKS REVALUATED PATHOLOGICAL DATA (ADDENDUM TO HRC-REPORT PDR171/75945) REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND DI - 4037 GLP: NO Published: NO	N	CHEM

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A6.6.1	KOORN,J.C.	1990	STUDY TO EXAMINE THE POSSIBLE MUTAGENIC ACTIVITY OF DIFLUBENZURON IN THE AMES SALMONELLA/MICROSOME ESSAY REPORT DUPHAR B.V., THE NETHERLANDS NO.56645/74/1990 DI - 7988 GLP: YES Published: NO	N	CHEM
A6.6.2	TAALMAN,R.D.F.M., HOORN,A.J.W.	1986	MUTAGENICITY EVALUATION OF DIFLUBENZURON TECHNICAL IN AN IN VITRO CYTOGENETIC ASSAY MEASURING CHROMOSOME ABERRATION FREQUENTIES IN CHINESE HAMSTER OVARY CELLS REPORT HAZLETON BIOTECHNOLOGIES, THE NETHERLANDS NO.56645/36/1986 DI - 5707 GLP: YES Published: NO	N	CHEM
A6.6.3	BRUSICK,D.J., WEIR,R.J.	1977	EVALUATION OF DIFLUBENZURON IN VITRO MALIGNANT TRANSFORMATION IN BALB/3T3 CELLS REPORT LITTON BIONETICS, U.S.A NO.56645/35/1977 DI - 2263 GLP: NO Published: NO	N	CHEM

Section No.	Author(s)	Year	Title Company, Report No GLP or GEP status Published or not	Data protection claimed Y/N	Owner
A6.6.4 (01)	MACGREGOR, J.T., GOULD, D.H., MITCHELL, A.D. AND STERLING G.P.	1979	MUTAGENICITY TESTS OF DIFLUBENZURON IN THE MICRONUCLEUS TEST IN MICE, THE L5178Y MOUSE LYMPHOMA FORWARD MUTATION ASSAY, AND THE AMES SALMONELLA REVERSE MUTATION TEST. MUTATION RESEARCH, 66 (1979) 45-53 GLP: NO Published: YES	N	
A6.6.4 (02)	ENNINGA,I.C.	1990	EVALUATION OF DNA REPAIR INDUCING ABILITY OF DIFLUBENZURON IN A PRIMARY CULTURE OF RAT HEPATOCYTES (WITH INDEPENDENT REPEAT) REPORT RCC NOTOX B.V., THE NETHERLANDS NO.56645/114/1990 DI - 7987 GLP: YES Published: NO	N	CHEM
A6.6.6	ARNOLD, D., KENNEDY, G.L AND KEPLINGER, M.L	1974	MUTAGENIC STUDY WITH TH 6040 IN ALBINO MICE REPORT FROM THOMPSON-HAYWARD CHEMICAL COMPANY NO 9973 DI-2348 GLP: NO Published: NO	N	CHEM
A6.7 (01)	BURDOCK,G.A., WOLFE,G.W., HEPNER,K.E., ALSAKER,R.D.,KOKA,M., PHIPPS,R.B.	1984	ONCOGENICITY STUDY IN RATS, DIFLUBENZURON REPORT HAZLETON LABORATORIES AMERICA INC., U.S.A NO.56645/08/1984 DI - 8147 GLP: YES Published: NO	N	CHEM

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A6.7 (02)	HUNTER,B., BATHAM,P., OFFER,J.M. et al .	1975	TUMORIGENICITY STUDY OF DU 112307 TO MICE. DIETARY ADMINISTRATION FOR 80 WEEKS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR170/75685 DI - 3525 GLP: NO Published: NO	N	CHEM
A6.7 (02)	BATHAM,P., OFFER,J.M.	1977	TUMORGENICITY OF DU 112307 TO MICE DIETARY ADMINISTRATION FOR 80 WEEKS REVALUATED PATHOLOGICAL DATA (PDR/170/75685) REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.56645/11/1977 DI - 3526 GLP: NO Published: NO	N	CHEM
A6.7 (02)	OFFER,J.M.	1977	TUMORGENICITY OF DU 112307 TO MICE. DIETARY ADMINISTRATION FOR 80 WEEKS. ADDENDUM: HISTOPATHOLOGICAL EXAMINATION OF ADDITIONAL TISSUES (PDR/250) REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.56645/31/1977 DI - 3527 GLP: NO Published: NO	N	CHEM

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A6.7 (03)	COLLEY,J., HEYWOOD,R., STREET,A.E. et al	1984	THE EFFECT OF DIFLUBENZURON GIVEN BY ORAL ADMINISTRATION WITH THE FEED ON TOXICITY AND TUMOUR DEVELOPMENT IN MALE AND FEMALE HC/CFLP MICE REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.56645/32/1984 DI – 8146 GLP: YES Published: NO	N	CHEM
A6.8.1 (01)	PALMER,A.K., HILL,P.A.	1975	EFFECT OF DU 112307 ON PREGNANCY OF THE RAT REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR192/74978 DI - 2349 GLP: NO Published: NO	N	CHEM
A6.8.1 (02)	KAVANAGH,P.	1987	DIFLUBENZURON ORAL (GAVAGE) RAT TERATOLOGY LIMIT STUDY REPORT TOXICOL LABORATORIES LTD., ENGLAND (NO.PHD/11/87) NO.56645/68/1987 DI - 6552 GLP: YES Published: NO	N	CHEM
A6.8.1 (03)	PALMER,A.K., HILL,P.A.	1975	EFFECT OF DU 112307 ON PREGNANCY OF THE NEW ZEALAND WHITE RABBIT REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR193/74937 DI - 2350 GLP: NO Published: NO	N	CHEM

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A6.8.1 (04)	KAVANAGH,P.	1987	DIFLUBENZURON ORAL (GAVAGE) RABBIT TERATOLOGY LIMIT STUDY REPORT TOXICOL LABORATORIES LTD., ENGLAND (NO.PHD/12/87) NO.56645/79/1987 DI - 6553 GLP: YES Published: NO	N	CHEM
A6.8.2 (01)	PALMER,A.K., HILL,P.A.	1975	EFFECT OF DU 112307 ON REPRODUCTIVE FUNCTION OF MULTIPLE GENERATIONS IN THE RAT REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR173/75954 DI - 3516 GLP: NO Published: NO	N	CHEM
A6.8.2 (02)	PALMER,A.K., ALLEN,P.A., HEYWOOD,R. et al .	1978	EFFECT OF DIETARY ADMINISTRATION OF DU 112307 ON REPRODUCTIVE FUNCTION OF ONE GENERATION IN THE RAT REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR244/78653 DI - 3462 GLP: NO Published: NO	N	CHEM
A6.8.2 (03)	BROOKER, A.J.	1995	DIFLUBENZURON TECHNICAL - THE EFFECT ON REPRODUCTIVE FUNCTION OF TWO GENERATIONS IN THE RAT REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND NO.56345/83/1994 DI – 9182 GLP: YES Published: NO	Y	CHEM

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A6.8.2 (03)	BROOKER, A.J.	1995	DIFLUBENZURON TECHNICAL - THE EFFECT ON REPRODUCTIVE FUNCTION ON TWO GENERATIONS IN THE RAT: ADDENDUM 1 - INDIVIDUAL PUPS BODY WEIGHTS REPORT HUNTINGDON RESEARCH CENTRE, ENGLAND PDR/569 DI - 9182 GLP: YES Published: NO	Y	CHEM
A6.13 (01)	GIFFORD, L.J. DUNSIRE, J.P.	1994	THE DISPOSITION OF [^{14}C]-DIFLUBENZURON IN THE LAYING HEN. REPORT INVERESK RESEARCH INTERNATIONAL, SCOTLAND NO. 56354/19/1993. D1-8935 GLP: YES PUBLISHED: NO		
A6.13 (01)	CNUBBEN N., H., P., BIE, A.,T.,M., J. DE, OMMEN B.VAN	1996	EXTRACTION, QUANTIFICATION, STORAGE STABILITY, METABOLITE PROFILING AND METABOLITE IDENTIFICATION OF ^{14}C-DIFLUBENZURON AND ITS METABOLITES IN EDIBLE TISSUES OF THE LAYING HEN. REPORT TNO NUTRITION AND FOOD RESEARCH INSTITUTE, THE NETHERLANDS. V94.426. DI – 8935 GLP: YES PUBLISHED: NO		
A6.13 (02)	CAMERON, B.D., DUNSIRE,J.P., GIFFORD, L. ET AL	1991	THE DISPOSITION OF [^{14}C] DIFLUBENZURON IN THE LACTATING GOAT; REPORT INVERESK RESEARCH INTERNATIONAL, SCOTLAND NO.56654/02/1990, DI - 7721 GLP: YES PUBLISHED: NO		

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A6.13 (02)	DYKSMAN, J.A.R., STELD, D.J.K. VAN DER, JOCHEM, E., *ET AL*	1990	A METHOD FOR THE DETERMINATION OF TRACE LEVELS OF 4-CHLOROANILINE IN GOAT MILK; DEVELOPMENT, VALIDATION AND APPLICATION. REPORT DUPHAR B.V., THE NETHERLANDS NO.56630/292/1989 GLP: YES PUBLISHED: NO		
A6.13 (02)	TIMMERMAN, B.E., ECK, M.P.E. VAN, RUIJTEN, H.M.	1990	CHARACTERIZATION OF RESIDUES OF [^{14}C] DIFLUBENZURON IN LACTATING GOAT; REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO. 56629/83/1990 GLP: YES PUBLISHED: NO		
A7.1.1.1.1/01	BOELHOUWERS, E.J., JOUSTRA, K.D., NIJSSEN, O.A., et al.	1988	HYDROLYSIS OF 14C-LABELLED DIFLUBENZURON IN BUFFER SOLUTIONS AT PH5, PH7 AND PH9 REPORT DUPHAR B.V., THE NETHERLANDS NO.56630/137/1988 - DI – 6799 GLP NOT PUBLISHED	Y	CHEM
A7.1.1.1.1/02	WHITRIGHT, R.R.	2003	HYDROLYSIS STUDY OF 14C-2,6-DIFLUOROBENZOIC ACID AND 14C-4-CHLOROPHENYLUREA REPORT CROMPTON STUDY NUMBER 2002-132 DI - 11716 GLP, UNPUBLISHED	Y	CHEM
A7.1.1.1.2/01	BOELHOUWERS, E.J., JOUSTRA, K.D., STEGMAN, K.H.	1988	PHOTODEGRADATION OF 14C-LABELLED DIFLUBENZURON IN WATER REPORT DUPHAR B.V., THE NETHERLANDS NO.56630/35/1988 - DI – 6689 GLP NOT PUBLISHED	Y	CHEM

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A7.1.1.1.2/02	VOORDEN, E.C. VAN DER	1993	PHOTODEGRADATION OF [14C]-DIFLUBENZURON IN WATER: AN ESTIMATION OF THE QUANTUM YIELD REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56353/75/1993 - DI – 6689 NO GLP NOT PUBLISHED	Y	CHEM
A7.1.1.2.1/01	LAAN,J.M.T.VAN DER, THUS,J.L.G.	1993	DETERMINATION OF THE BIODEGRADABILITY OF 14C-DIFLUBENZURON IN AN ADAPTED MODIFIED STURM TEST REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/41/1993 DI - 8688 GLP, UNPUBLISHED	Y	CHEM
A7.1.2.2.2/01	THUS,J.L.G., LAAN,J.M.T.VAN DER .	1994	FATE OF DIFLUBENZURON IN TWO MODEL DITCH SYSTEMS REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/55/1993 DI - 8916 GLP, UNPUBLISHED	Y	CHEM
A7.1.2.2.2/02	VOELKEL,W.	1999	14C-DIFLUBENZURON: ROUTE AND RATE OF DEGRADATION IN AEROBIC AQUATIC SYSTEMS REPORT RCC LTD ENVIRONMENTAL CHEMISTRY AND PHARMANALYTICS DIVISION, SWITZERLAND NO.693707 (UCC STUDY NO. C.303.62.043) DI - 11425 GLP, UNPUBLISHED	Y	CHEM

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A7.1.2.2.2/03	DIJK, N.R.M.	1994	MICROBIAL DEGRADATION OF DIFLUBENZURON IN SURFACE WATER. SOLVAY DUPHAR B.V. NO. 56835/53/93 DI- 8956 GLP NOT PUBLISHED	Y	CHEM
A7.1.2.2.2/04	KNUTH, M. L..	1995	APPLICATION, DISTRIBUTION AND PERSISTENCE OF DIFLUBENZURON IN THE LITTORAL ENCLOSURE WATER COLUMN. CHAPTER 2 IN "EFFECTS, PERSISTENCE AND DISTRIBUTION OF DIFLUBENZURON IN LITTORAL ENCLOSURES REPORT EPA, NO 2898, U.S.A. – DI –9444 NON GLP PUBLISHED	N	-
A7.1.2.2.2/05	HEINIS L. J.	1995	DISTRIBUTION, PERSISTENCE, AND MASS BALANCE OF DIFLUBENZURON IN LITTORAL ENCLOSURES. CHAPTER 3 IN "EFFECTS, PERSISTENCE AND DISTRIBUTION OF DIFLUBENZURON IN LITTORAL ENCLOSURES REPORT EPA, NO 2898, U.S.A. NON GLP PUBLISHED	Y	CHEM
A7.2.1/01	WALSTRA,P., JOUSTRA,K.D. .	1990	AEROBIC SOIL METABOLISM OF DIFLUBENZURON IN SANDY LOAM REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/65/1990 DI – 8045 GLP, UNPUBLISHED	Y	CHEM

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A7.2.2.1/01	GAAUW VAN DER, A.	2003	DEGRADATION RATE OF DIFLUBENZURON IN THREE SOILS INCUBATED UNDER AEROBIC CONDITIONS REPORT RCC, SWITZERLAND NO.: 844498 DI -11734 GLP, UNPUBLISHED	Y	CHEM
A7.2.2.1/02	PIJST, H.L.A., GAAUW VAN DER, A.	2004	DEGRADATION KINETICS OF DIFLUBENZURON AND ITS MAIN METABOLITES CPU AND DFBA IN AN AEROBIC DEGRADATION STUDY IN 3 SOILS USING MODELMAKER REPORT CROMPTON EUROPE B.V. NO.AM950/07/2004 DI –11734	Y	CHEM
A7.2.2.1/03	WILLEMS, A.G.M., JOUSTRA, K.D.	1984	DEGRADATION OF 2,6-DIFLUOROBENZOIC ACID IN SOIL. REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/02/1984 GLP, UNPUBLISHED	Y	CHEM
A7.2.2.4/01	SAXENA,A.M., MARSH,S.S., KOEBEL,D.D.	1991	PHOTODEGRADATION OF 14C-DIFLUBENZURON ON A SANDY LOAM SOIL UNDER ARTIFICIAL SUNLIGHT IRRADIATION REPORT BATELLE, U.S.A. NO.56630/215/1991 DI - 8424 NOT GLP, UNPUBLISHED	Y	CHEM
A7.2.2.4/02	THUS,J.L.G, DIJK,N.R.M.VAN , ROMPA-VELDT,C.A.H. et al .	1991	ANAEROBIC AQUATIC METABOLISM OF DIFLUBENZURON REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/34/1991 DI – 8133 GLP, UNPUBLISHED	Y	CHEM

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A7.2.2.4/03	THUS,J.L.G., DIJK,N.R.M.VAN	1991	ANAEROBIC AQUATIC METABOLISM OF DIFLUBENZURON. ADDENDUM REPORT REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/54/1991 DI – 8133 GLP, UNPUBLISHED	Y	CHEM
A7.2.2.4/04	SCHOCKEN,M.J.	2000	RATE OF ANAEROBIC DEGRADATION OF 4-CHLOROPHENYLUREA AND 2,6-DIFLUOROBENZOIC ACID. REPORT UNIROYAL CHEMICAL COMPANY, INC., U.S.A., NO.2000-119 NOT GLP, UNPUBLISHED	Y	CHEM
A7.2.3.1/01	BOOTH, G.M., JACKSON, C. , EASTMOND, D.	1980	THE ADSORPTION AND DESORPTION OF 14C-DIMILIN TO EIGHT SOIL TYPES. REPORT BRIGHAM YOUNG UNIVERSITY, U.S.A. NOT GLP, UNPUBLISHED	Y	CHEM
A7.2.3.1/02	NIMMO, W.B. .	1986	ADSORPTION OF DIFLUBENZURON TO SOILS REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/07/1986 DI - 5365 NONGLP, UNPUBLISHED	Y	CHEM
A7.2.3.1/03	ADAM, D.	2004	ADSORPTION OF 14C-DIFLUBENZURON ON TWO SOILS REPORT RCC LTD – SWITZERLAND NO. 857789 DI – 11797 GLP, UNPUBLISHED	Y	CHEM

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A7.2.3.1/04	DIJK,N.R.M., VAN .	1992 a	ADSORPTION/DESORPTION TEST WITH 4-CHLOROPHENYLUREA WITH FOUR SOIL TYPES REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56635/54/1992 DI - 8626 GLP, UNPUBLISHED	Y	CHEM
A7.2.3.1/05	DIJK,N.R.M., VAN .	1992 b	ADSORPTION/DESORPTION TEST WITH DIFLUOROBENZOIC ACID WITH THREE SOIL TYPES REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56635/24/1992 DI - 8557 GLP, UNPUBLISHED	Y	CHEM
A7.2.3.2/01	DIJK,N.R.M., VAN	1995	LEACHING OF FORMULATED DIFLUBENZURON IN THREE SOILS REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/54/1994 DI - 9336 GLP, UNPUBLISHED	Y	CHEM
A7.3.1/01	SCHOCKEN, M.J.	1999	GAS-PHASE OXIDATION RATE AND HALF-LIFE OF DIFLUBENZURON IN THE TROPOSPHERE REPORT UNIROYAL CHEMICAL INC., U.S.A. NO.99115 - DI – 11460 NO GLP NOT PUBLISHED	Y	CHEM

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A7.4.1.1/01	MARSHALL, B.L.	1973	96-HOURS LC_{50} STUDIES WITH TH 6040 TECHNICAL AND WETTABLE POWDER FORMULATIONS ON SALT WATER MINNOW, FRESH WATER TROUT AND SUNFISH REPORT MARINE RESEARCH INSTITUTE, MASSACHUSETTS, U.S.A. FW-19 DI - 3611 NO GLP UNPUBLISHED	Y	CHEM
A7.4.1.1/02	BERENDS,A.G., LAAN,J.M.T.VAN DER .	1994a	THE ACUTE TOXICITY OF DIFLUBENZURON TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/02/1994 DI - 8926	Y	CHEM
A7.4.1.1/03	REINERT,H.K., PARKE,G.ST.E	1975	REPORT STATIC 96 HOUR TOXICITY STUDY OF THOMPSON-HAYWARD CHEMICAL COMPANY SAMPLE TH 6040 IN FATHEAD MINNOWS REPORT CANNON LABORATORIES INC., U.S.A. NO.5E-6095 DI - 3630 NO GLP UNPUBLISHED	Y	CHEM
A7.4.1.1/04	NICHOLSON, R.B.	1987	ACUTE TOXICITY OF DIFLUBENZURON TECHNICAL TO SHEEPSHEAD MINNOW (*CYPRINODON VARIEGATUS*) REPORT SPRINGBORN BIONOMICS INC., U.S.A. NO.56635/26/1987 DI - 6152 GLP UNPUBLISHED	Y	CHEM

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A7.4.1.1/05	GRAVES,W.C., SWIGERT,J.P.	1993	DIFLUBENZURON: A 96-HOUR FLOW-THROUGH ACUTE TOXICITY TEST WITH THE SHEEPSHEAD MINNOW (*CYPRINODON VARIEGATUS*) REPORT WILDLIFE INTERNATIONAL LTD., U.S.A. NO.56835/13/1993 DI - 8668 GLP UNPUBLISHED	Y	CHEM
A7.4.1.1/06	BERENDS,A.G., LAAN,J.M.T.VAN DER .	1994b	THE ACUTE TOXICITY OF DIFLUBENZURON TO ZEBRA FISH (*BRACHYDANIO RERIO*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/57/1993 DI - 8925 GLP UNPUBLISHED	Y	CHEM
A7.4.1.1/07	GROENEVELD,A.H.C., BERENDS,A.G. .	1993	THE ACUTE TOXICITY OF 4-CHLOROPHENYLUREA TO THE ZEBRA FISH (*BRACHYDANIO RERIO*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/49/1993 DI - 8825	Y	CHEM
A7.4.1.1/08	GROENEVELD,A.H.C., DIJK,N.R.M.VAN , BERENDS,A.G.	1993	THE ACUTE TOXICITY OF 2,6-DIFLUOROBENZOIC ACID TO THE ZEBRA FISH (*BRACHYDANIO RERIO*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/47/1993 DI - 8802	Y	CHEM

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A7.4.1.1/09	BERENDS, A.G., LAAN, J.M.T. VAN DER	1994c	THE ACUTE TOXICITY OF DIMILIN WG-80 TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO. 56835/03/1994 DI-8927 GLP NOT PUBLISHED	Y	CHEM
A7.4.1.1/10	BERENDS, A.G., LAAN, J.M.T. VAN DER	1994d	THE ACUTE TOXICITY OF DIMILIN WG-80 TO ZEBRA FISH (*BRACHYDANIO RERIO*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/62/1993 DI - 8929 GLP NOT PUBLISHED	Y	CHEM
A7.4.1.2/01	KUIJPERS,L.A.M.	1988	THE ACUTE TOXICITY OF DIFLUBENZURON TO *DAPHNIA MAGNA* REPORT DUPHAR B.V., THE NETHERLANDS NO.56635/26/1988 DI - 6773	Y	CHEM
A7.4.1.2/02	GROENEVELD,A.H.C., PHILIPS,T.M.W., THUS,J.L.G.	1995	THE ACUTE TOXICITY OF DIMILIN WG-80 TO *DAPHNIA MAGNA* COMPARED TO DIFLUBENZURON REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/45/1994 DI - 9180 GLP NOT PUBLISHED	Y	CHEM

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A7.4.1.2/03	SURPRENANT,D.C.	1989	ACUTE TOXICITY OF DIFLUBENZURON TO QUAHOGS (*MERCENARIA MERCENARIA*) EMBRYO-LARVAE UNDER STATIC CONDITIONS REPORT SPRINGBORN LABORATORIES INC. U.S.A. NO.56635/10/1989 DI - 7597 GLP UNPUBLISHED	Y	CHEM
A7.4.1.2/04	GROENEVELD,A.H.C., THUS,J.L.G..	1993	THE ACUTE TOXICITY OF 4-CHLOROPHENYLUREA TO *DAPHNIA MAGNA* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/45/1993 DI - 8800 GLP UNPUBLISHED	Y	CHEM
A7.4.1.2/05	GROENEVELD,A.H.C., DIJK,N.R.M.VAN, KEETELAAR-JANSEN,W. *et al* .	1993	THE ACUTE TOXICITY OF 2,6-DIFLUOROBENZOIC ACID TO *DAPHNIA MAGNA* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/48/1993 DI - 8826 GLP UNPUBLISHED	Y	CHEM
A7.4.1.3/01	BERENDS,A.G., THUS,J.L.G. .	1992	THE TOXICITY OF DIFLUBENZURON TO THE ALGA *SELENASTRUM CAPRICORNUTUM* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56635/49/1992 DI - 8587 GLP UNPUBLISHED	Y	CHEM

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A7.4.1.3/02	THOMPSON,S.G. , SWIGERT,J.P.	1993a	DIFLUBENZURON: A 5-DAY TOXICITY TEST WITH THE FRESHWATER ALGA (*SELENASTRUM CAPRICORNUTUM*) REPORT WILDLIFE INTERNATIONAL LTD., U.S.A. NO.56835/23/1993 DI - 8667 GLP UNPUBLISHED	Y	CHEM
A7.4.1.3/03	THOMPSON,S.G. , SWIGERT,J.P.	1993b	DIFLUBENZURON: A 5-DAY TOXICITY TEST WITH THE FRESHWATER ALGA (*ANABAENA FLOS-AQUAE*) REPORT WILDLIFE INTERNATIONAL LTD., U.S.A. NO.56835/21/1993 DI - 8669 GLP UNPUBLISHED	Y	CHEM
A7.4.1.3/04	KEETELAAR,W. A.J., LAAN,J.M.T.VA N DER, BERENDS,A.G. .	1994	THE TOXICITY OF 4-CHLOROPHENYLUREA TO THE ALGA *SELENASTRUM CAPRICORNUTUM* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/19/1994 DI - 8942 GLP UNPUBLISHED	Y	CHEM
A7.4.1.3/05	GROENEVELD,A .H.C., DIJK,N.R.M., BERENDS,A.G. .	1995	THE TOXICITY OF 2,6-DIFLUOROBENZOIC ACID TO THE ALGA *SELENASTRUM CAPRICORNUTUM* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/23/1994 DI - 9181 GLP UNPUBLISHED	Y	CHEM

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A7.4.1.3/06	GROENEVELD,A.H.C., KEETELAAR,W.A.J., ALLAN,E. et al .	1994	THE TOXICITY OF DIMILIN WG-80 TO THE ALGA *SELENASTRUM CAPRICORNUTUM* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/20/1994 DI - 9104 GLP NOT PUBLISHED	Y	CHEM
A7.4.1.4/01	MEAD, C	2002	DIFLUBENZURON: ASSESSMENT OF THE INHIBITORY EFFECT ON THE RESPIRATION OF ACTIVATED SEWAGE SLUDGE REPORT SAFEPHARM LABORATORIES LTD., UNITED KINGDOM NO.1133/012 DI – 11692 GLP UNPUBLISHED	Y	CHEM
A7.4.2/01	BURGESS, D.	1989	UPTAKE, DEPURATION AND BIOCONCENTRATION OF 14C-DIFLUBENZURON BY BLUEGILL SUNFISH (*LEPOMIS MACROCHIRUS*) REPORT BIO-CHEMISTRY LABORATORIES, INC., U.S.A. NO.56635/16/1989 DI - 7477 GLP UNPUBLISHED	Y	CHEM
A7.4.2/02	BOELHOUWERS,E.J., JOUSTRA,K.D., STEGMAN,K.	1992	IDENTIFICATION OF 14C-RESIDUES IN AQUARIUM WATER, FILLET, WHOLE FISH AND VISCERA SAMPLES OF BLUEGILL SUNFISH FROM AN ACCUMULATION STUDY WITH 14C-DIFLUBENZURON REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56630/08/1991 DI - 7477 GLP UNPUBLISHED	Y	CHEM

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A7.4.3/01	Corry, T., Stay, F.S., Knuth, M.L.	1995	CHAPTER SIX IN EFFECTS, PERSISTENCE AND DISTRIBUTION OF DIFLUBENZURON IN LITTORAL ENCLOSURES REPORT EPA. NO 2898, U.S.A DI – 9444 NO GLP PUBLISHED	Y	CHEM
A7.4.3/02	MOFFETT, M.F., KNUTH, M.L., HEINIS, L.J.	1995	EFFECTS, PERSISTENCE AND DISTRIBUTION OF DIFLUBENZURON IN LITTORAL ENCLOSURES REPORT EPA. NO 2898, U.S.A DI – 9444 NO GLP PUBLISHED	Y	CHEM
A7.4.3/03	PJIST, H.L.A, WYNESS, L.	2005	RISK ASSESSMENT OF DIFLUBENZURON ON AQUATIC ORGANISMS WITH PARTICULAR EMPHASIS ON AQUATIC INVERTEBRATES REPORT CROMPTON EUROPE B.V. AM950-20-2004; D1-11802	Y	CHEM
A7.4.3.1/01	BERENDS,A.G., GROENEVELD,A.H.C., ALLAN,E. *et al*	1994	THE SEMI-CHRONIC TOXICITY OF DIFLUBENZURON TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/35/1994 DI - 9179 GLP UNPUBLISHED	Y	CHEM
A7.4.3.4/01	SURPRENANT,D.C.	1988	THE CHRONIC TOXICITY OF 14C-DIFLUBENZURON TO *DAPHNIA MAGNA* UNDER FLOW-THROUGH CONDITIONS REPORT SPRINGBORN LIFE SCIENCES INC., U.S.A. NO.56635/22/1988 DI - 6772 GLP UNPUBLISHED	Y	CHEM

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A7.4.3.4/02	BRETELER,R.J.	1987a	CHRONIC TOXICITY OF DIFLUBENZURON TO MYSID SHRIMP (*MYSIDOPSIS BAHIA*) REPORT SPRINGBORN BIONOMICS INC., U.S.A. NO.56635/20/1987 DI - 6093 GLP UNPUBLISHED	Y	CHEM
A7.4.3.4/03	BRETELER,R.J.	1987b	CHRONIC TOXICITY OF DIFLUBENZURON TO MYSID SHRIMP (*MYSIDOPSIS BAHIA*), PART II, SUPPLEMENTAL STUDIES REPORT SPRINGBORN BIONOMICS INC., U.S.A. NO.56635/25/1987 DI - 6093 GLP UNPUBLISHED	Y	CHEM
A7.4.3.5.2/01	THOMPSON,S.G., SWIGERT,J.P	1993c	DIFLUBENZURON: A 14-DAY TOXICITY TEST WITH DUCKWEED (*LEMNA GIBBA* G3) REPORT WILDLIFE INTERNATIONAL LTD., U.S.A. NO.56835/22/1993 DI - 8670 GLP UNPUBLISHED		
A7.5.1.1/01	THUS, J.L.G., LAAN, J.M.T. VAN DER, KEETELAAR-JANSEN, W.	1995	EFFECTS OF DIMILIN WG-80 ON THE ACTIVITY OF SOIL MICROFLORA: SHORT TERM RESPIRATION AND NITROGEN MINERALIZATION REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56835/50/1994 DI - 9327 GLP UNPUBLISHED	Y	CHEM

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A7.5.1.1/02	KEETELAAR-JANSEN, W. LAAN, J.M.T. VAN DER, THUS, J.L.G.	1995	EFFECT OF DIMILIN WG-80 ON THE ACTIVITY OF SOIL MICROFLORA: NITROGEN MINERALISATION DURING 3 MONTHS REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56834/03/1995 DI - 9328 NO GLP UNPUBLISHED	Y	CHEM
A7.5.1.2/01	BERENDS,A.G., THUS,J.L.G., JANSEN,W.A.J.	1992	THE ACUTE TOXICITY OF DIFLUBENZURON TO THE EARTHWORM *EISENIA FETIDA* REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56635/22/1992 DI - 8580	Y	CHEM
A7.5.1.2/02	WETTON, P.M.	2002a	4-CHLOROPHENYLUREA (CPU): ACUTE TOXICITY TO EARTHWORMS (*EISENIA FOETIDA*) REPORT SAFEPHARM LABORATORIES LTD., UNITED KINGDOM NO.1133/014 DI - 11696	Y	CHEM
A7.5.1.2/03	WETTON, P.M.	2002b	2,6-DIFLUOROBENZOIC ACID (DFBA): ACUTE TOXICITY TO EARTHWORMS (*EISENIA FOETIDA*) REPORT SAFEPHARM LABORATORIES LTD., UNITED KINGDOM NO.1133/015 DI – 11697 GLP UNPUBLISHED	Y	CHEM
A7.5.1.2/04	BERENDS, A.G, THUS, J.L.G., JANSEN, W.A.J	1992	THE ACUTE TOXICITY OF DIFLUBENZURON TO THE EARTHWORM EISENIA FETIDA REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56635/22/1992 DI - 8580	Y	CHEM

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A7.5.3.1.1/01	ALSAGER,D.E.	1975	ACUTE ORAL TOXICITY STUDIES (LD50) OF TH6040 INSECTICIDE TO RED WINGED BLACKBIRDS (*AGELAIUS PHOENICEUS*) REPORT CANADIAN BIO-SCIENTIFIC CONSULTANTS LTD., CANADA FW-6 DI - 3606 NO GLP UNPUBLISHED	Y	CHEM
A7.5.3.1.1/02	HUDSON,R.H.	1975	DIMILIN APPLIED TO MALLARDS REPORT THOMPSON-HAYWARD CHEMICAL COMPANY, U.S.A. NO.C3683 DI - 3056 NO GLP UNPUBLISHED	Y	CHEM
A7.5.3.1.1/03	PARKE,G.ST.E.	1976a	STUDY: ACUTE ORAL TOXICITY IN MALLARD DUCKS. COMPOUND: TH6040 99.4% PURE (AIR MILLED) REPORT CANNON LABORATORIES INC., U.S.A. FW-27,LAB.NO.6E-2430 DI - 3597 NO GLP UNPUBLISHED	Y	CHEM
A7.5.3.1.1/04	PARKE,G.ST.E.	1976b	STUDY: ACUTE ORAL TOXICITY IN BOBWHITE QUAIL. COMPOUND: TH 6040 99.4% PURE (AIR MILLED) REPORT CANNON LABORATORIES INC., U.S.A. FW-26,L.NO.6E-2430 A DI – 3598 NO GLP UNPUBLISHED	Y	CHEM

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A7.5.3.1.2/ 01	FINK, R.	1973a	EIGHT-DAY DIETARY LC50 - MALLARD DUCKS TECHNICAL TH-6040 FINAL REPORT REPORT HAZLETON LABORATORIES AMERICA INC., U.S.A. FW-4 DI - 3603 NO GLP UNPUBLISHED	Y	CHEM
A7.5.3.1.2/ 02	FINK, R.	1973b	EIGHT-DAY DIETARY LC50 - BOBWHITE QUAIL TECHNICAL TH-6040 FINAL REPORT REPORT HAZLETON LABORATORIES AMERICA INC., U.S.A. FW-5 DI - 3604 NO GLP UNPUBLISHED	Y	CHEM
A7.5.3.1.3/ 01	BEAVERS,J.B., CORBITT,A., HAWROT,R. et al	1990a	A ONE-GENERATION REPRODUCTION STUDY WITH THE MALLARD (*ANAS PLATYRHYNCHOS*) REPORT WILDLIFE INTERNATIONAL LTD., U.S.A. NO.56645/07/1990 DI - 7945 GLP UNPUBLISHED	Y	CHEM
A7.5.3.1.3/ 02	BEAVERS,J.B., CORBITT,A., HAWROT,R. et al	1990b	A ONE-GENERATION REPRODUCTION STUDY WITH THE BOBWHITE (*COLINUS VIRGINIANUS*) REPORT WILDLIFE INTERNATIONAL LTD., U.S.A. NO.56645/08/1990 DI - 7946 GLP UNPUBLISHED	Y	CHEM

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A7.5.4/01	TORNIER, I	1995b	ASSESSMENT OF THE SIDE EFFECTS OF DIMILIN WG-80 ON THE HONEY BEE (*APIS MELLIFERA* L.) IN THE SEMI-FIELD AT TWO DIFFERENT LOCATIONS REPORT ARBEITSGEMEINSCHAFT GAB BIOTECHNOLOGIE UND IFU UMWELTANALYTIK94007/01-BZBB DI - 9391 GLP NOT PUBLISHED	Y	CHEM
A7.5.4/02	TORNIER, I	1995C	ASSESSMENT OF SIDE EFFECTS OF DIMILIN WG-80 ON THE HONEY BEE (*APIS MELLIFERA* L.) IN THE FIELD BY APPLICATION DURING BEE-FLIGHT REPORT ARBEITSGEMEINSCHAFT GAB BIOTECHNOLOGIE UND IFU UMWELTANALYTIK94007/01-BFBB DI - 9386 GLP NOT PUBLISHED	Y	CHEM
A7.5.4/03	KUIJPERS,L.A.M.	1993	THE IMPACT OF DIMILIN ON HONEY-BEES: A REVIEW REPORT SOLVAY DUPHAR B.V., THE NETHERLANDS NO.56635/29/1992 DI – 7234 NO GLP UNPUBLISHED	Y	CHEM
A7.5.4/04	BEUSCHEL, S.	2006	DIMILIN WG 80: ASSESSMENT OF SIDE EFFECTS TO THE HONEY BEE (APIS MELLIFERA L.) IN THE FIELD FOLLOWING APPLICATION DURING BEE-FLIGHT IN GERMANY 2005	Y	CHEM

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A7.5.4/05	BAXTER, I	1999	A LABORATORY TEST TO DETERMINE THE EFFECT OF DIMILIN WG-80 (A 800 G/KG WG FORMULATION OF DIFLUBENZURON) ON THE PARASITIC WASP *APHIDIUS RHOPALOSIPHI* REPORT AGROCHEMICAL EVALUATION UNIT, UNITED KINGDOM, NO.UNI-99-5 DI-11466 GLP UNPUBLISHED	Y	CHEM
A7.5.4/06	VINALL, S.	1999a	A LABORATORY TEST TO DETERMINE THE EFFECT OF DIMILIN WG-80 (A 800 G/KG WG FORMULATION OF DIFLUBENZURON) ON THE PREDATORY MITE *TYPHLODROMUS PYRI* REPORT AGROCHEMICAL EVALUATION UNIT, UNITED KINGDOM, NO.UNI-99-6 DI-11463	Y	CHEM
A7.5.4/07	VINALL, S	1999b	A LABORATORY TEST TO DETERMINE THE EFFECT OF DIMILIN WG-80 (AN 800G/KG WG FORMULATION OF DIFLUBENZURON) ON THE GROUND-ACTIVE BEETLE, *ALEOCHARA BILINEATA* REPORT AGROCHEMICAL EVALUATION UNIT, UNITED KINGDOM NO.UNI-99-7 (UNIROYAL REF. NO. C.303.51.046) DI – 11501 GLP UNPUBLISHED	Y	CHEM

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A7.5.4/08	TORNIER, I	1995a	ASSESSMENT OF SIDE EFFECTS OF DIMILIN WG-80 ON LARVAE OF THE HOVERFLY, *EPISYRPHUS BALTEATUS* DEG. (DIPTERA, SYRPHIDAE) UNDER SEMI FIELD CONDITIONS REPORT ARBEITSGEMEINSCHAFT GAB BIOTECH. UND IFU UMWELTANALYTIC,GERMANY 94007/01-NHEB DI - 9395	Y	CHEM
A7.5.4/09	TORNIER, I	1995d	ASSESSMENT OF SIDE EFFECTS OF DIMILIN WG-80 ON LARVAE OF LADY BIRD BEETLE, *COCCINELLA SEPTEMPUNCTATA* L.(COLEOPTERA, COCCINELLIDAE) UNDER SEMIFIELD CONDITIONS REPORT ARBEITSGEMEINSCHAFT GAB BIOTECHNOLOGIE UND IFU UMWELTANALYTIK 94007/01-NHCS DI - 9392	Y	CHEM
A7.5.4/10	HALSALL, N	2002	DIMILIN WG-80: AN EXTENDED LABORATORY RATE-RESPONSE TEST TO DETERMINE EFFECTS ON THE LADYBIRD BEETLE, *COCCINELLA SEPTEMPUNCTATA* MAMBO-TOX NO.: UNI-02-9, NO.: C.303.51.052 DI-11705 GLP UNPUBLISHED	Y	CHEM
A7.5.4/11	MANLEY, B	2002	A RATE-RESPONSE EXTENDED LABORATORY TEST TO DETERMINE THE EFFECTS OF DIMILIN WG-80 (AN 800 G/KG FORMULATION OF DIFLUBENZURON) ON THE GREEN LACEWING, *CHRYSOPERLA CARNEA* MAMBO-TOX NO.UNI-02-8; NO.C.303.51.051 DI-11708	Y	CHEM

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A7.5.4/12	PIJST, H.L.A., WYNESS, L, MEAD-BRIGGS, M., GROSSCURT, A.C.	2004	RISK ASSESSMENT ON NON-TARGET ARTHROPODS WITH PARTICULAR RELEVANCE TO ORCHARDS AND FOREST ENVIRONMENTS REPORT CROMPTON EUROPE B.V. THE NETHERLANDS AM950-16-2004; DI- 11801	Y	CHEM
A7.5.6/01	GROSSCURT, A.R.C.	2000	SUMMARY OF THE BIOLOGICAL ACTIVITY OF DIFLUBENZURON IN PRELIMINARY LABORATORY TESTS REPORT UNIROYAL CHEMICAL EUROPE B.V., NO.880/04HA/2000 NO GLP UNPUBLISHED	Y	CHEM

List of studies generated as confirmatory data under Directive 91/414/EEC

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	KRSMANOVIC, L	2011	GENOTOXIC ASSESSMENT OF PARA-CHLOROANILINE (PCA) FOLLOWING ORAL ADMINISTRATION 1. MICROSCOPIC EVALUATION OF MOUSE BONE MARROW FOR PRESENCE OF MICRONUCLEATED POLYCHROMATIC ERYTHROCYTES 2. FLOW CYTOMETRIC EVALUATION OF MOUSE PERIPHERAL BLOOD FOR PRESENCE OF MICRONUCLEATED RETICULOCYTES BIO RELIANCE 9630 MEDICAL CENTER DRIVE ROCKVILL, MD 20850	Y	CHEM
	PANT, K AND CELESTIN, N	2011	PARA-CHLOROANILINE (PCA): UNSCHEDULED DNA SYNTHESIS (UDS) TEST WITH MAMMALIAN CELLS IN VIVO BIORELIANCE, 9630 MEDICAL CENTER DRIVE, ROCKVILLE LABORATORY STUDY NUMBER AD15NJ.381.BTL	Y	CHEM
	PANT, K AND CELESTIN, N	2011	PARA-CHLOROANILINE (PCA): COMET ASSAY IN RAT PERIPHERAL BLOOD, LIVER AND SPLEEN CELLS FOLLOWING ORAL ADMINISTRATION BIORELIANCE, 9630 MEDICAL CENTER DRIVE, ROCKVILLE LABORATORY STUDY NUMBER AD15NJ.423.BTL	Y	CHEM

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	JOHNSON, S	2010	DIFLUBENZURON: COMPARATIVE IN VITRO METABOLISM STUDY USING RAT, PIG, GOAT AND HUMAN HEPATOCYTES HUNTINGDON LIFE SCIENCES PROJECT IDENTITY FDD0042	Y	CHEM