

## **CLH report**

### **Proposal for Harmonised Classification and Labelling**

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),  
Annex VI, Part 2**

**Substance Name: Dichlofluanid**

**EC Number: 214-118-7**

**CAS Number: 1085-98-9**

**Index Number: 616-006-00-7**

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# Part A.

## 1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

### 1.1 Substance

**Table 1: Substance identity**

<b>Substance name:</b>	Dichlofluanid
<b>EC number:</b>	214-118-7
<b>CAS number:</b>	1085-98-9
<b>Annex VI Index number:</b>	616-006-00-7
<b>Degree of purity:</b>	≥ 96% (Typical 98%)
<b>Impurities:</b>	Confidential – full information on the impurities is provided in the technical dossier. None of the identified impurities are relevant for classification and labelling.

### 1.2 Harmonised classification and labelling proposal

**Table 2: The current Annex VI entry and the proposed harmonised classification**

	<b>CLP Regulation</b>
<b>Current entry in Annex VI, CLP Regulation</b>	Skin Sens 1; H317 – May cause an allergic skin reaction  Eye Irrit 2; H319 – Causes serious eye irritation  Acute Tox 4* H332 – Harmful if inhaled  Aquatic Acute 1 ; H400 – Very toxic to aquatic life  M=10
<b>Current proposal for consideration by RAC</b>	Skin Sens 1B; H317 – May cause an allergic skin reaction  Acute Tox 4; H332 0 Harmful if inhaled
<b>Resulting harmonised classification (future entry in Annex VI, CLP Regulation)</b>	Skin Sens 1B; H317 – May cause an allergic skin reaction

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	<p>Eye Irrit 2; H319 - Causes serious eye irritation</p> <p>Acute Tox 4; H332 - H332 – Harmful if inhaled</p> <p>Aquatic Acute 1; H400 - Very toxic to aquatic life</p> <p>M=10</p>
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### 1.3 Proposed harmonised classification and labelling

**Table 3: Proposed classification**

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification <sup>1)</sup>	Reason for no classification <sup>2)</sup>
2.1.	Explosives	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.2.	Flammable gases	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.3.	Flammable aerosols	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.4.	Oxidising gases	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.5.	Gases under pressure	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.6.	Flammable liquids	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.7.	Flammable solids	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.9.	Pyrophoric liquids	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.10.	Pyrophoric solids	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.11.	Self-heating substances and mixtures	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.12.	Substances and mixtures which in contact with water emit flammable gases	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.13.	Oxidising liquids	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.14.	Oxidising solids	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
2.15.	Organic peroxides	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification

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2.16.	Substance and mixtures corrosive to metals	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.1.	Acute toxicity - oral	<b>Acute Tox 4; H332 – Harmful if inhaled</b>	Not applicable	<b>Acute Tox 4*; H332 – Harmful if inhaled</b>	
	Acute toxicity - dermal	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
	Acute toxicity - inhalation	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation	<b>Eye Irrit 2; H319 – causes serious eye irritation</b>	Not applicable	<b>Eye Irrit 2; H319 – causes serious eye irritation</b>	
3.4.	Respiratory sensitisation	Not classified	Not applicable	Not classified	Data lacking
3.4.	Skin sensitisation	<b>Skin Sens 1B; H317 – may cause an allergic skin reaction</b>	Not applicable	<b>Skin Sens 1; H317 – may cause an allergic skin reaction</b>	
3.5.	Germ cell mutagenicity	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.6.	Carcinogenicity	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.7.	Reproductive toxicity	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.8.	Specific target organ toxicity – single exposure	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
3.10.	Aspiration hazard	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification
4.1.	Hazardous to the aquatic environment	<b>Aquatic Acute 1; H400 – very toxic to aquatic life</b>	<b>M = 10</b>	<b>Aquatic Acute 1; H400 – very toxic to aquatic life</b>	
5.1.	Hazardous to the ozone layer	Not classified	Not applicable	Not classified	conclusive but not sufficient for classification

<sup>1)</sup> Including specific concentration limits (SCLs) and M-factors

<sup>2)</sup> Data lacking, inconclusive, or conclusive but not sufficient for classification



**Labelling:**

Pictogram(s): GHS07, GHS09

Signal word: Warning

Hazard statements: H317, H319, H332, H400

Precautionary statements: Not included in Annex VI

**Proposed notes assigned to an entry:**

None

## **2 BACKGROUND TO THE CLH PROPOSAL**

### **2.1 History of the previous classification and labelling**

Dichlofluanid is a biocidal active substance in the scope of Reg 528/2012. The substance was first included in Annex I to Dir 67/548/EEC at the 25<sup>th</sup> ATP (1998), with the following classification and labelling Xn; R20, Xi; R36, R43, N; R50-53 in accordance with DSD. The classification and labelling was reviewed in 1999 by the Working Group on the classification and labelling of Dangerous Substances – Pesticides (May and November 1999 meetings), where it was concluded that the existing classification was appropriate. During this time, the substance was also discussed by the Specialised Experts. In March-April 2004, the classification was discussed at the Meeting on Environmental Effects of Existing Chemicals, Pesticides and New Chemicals, where it was agreed to remove the R53 classification.

At the entry into force of CLP, the classification in table 3.1 of Annex VI to CLP was translated as Skin Sens 1; H317, Eye Irrit 2; H319, Acute Tox 4\*; H332, Aquatic Acute 1; H400 and Aquatic Chronic 1: H410. The classification in Annex VI of CLP was updated at the 1<sup>st</sup> ATP to CLP to remove the classification for Aquatic Chronic 1; H410 and to include the acute M factor.

At the time of submission, the substance does not have a separate REACH registration as it is an active biocide substance.

It should be noted that dichlofluanid was also a pesticidal active substance within scope of Directive 91/414/EEC. However, it was not approved in the EU as the necessary dossier was not submitted in the specified timeframe (Regulation 2076/2002).

### **2.2 Short summary of the scientific justification for the CLH proposal**

Dichlofluanid already has an existing entry in Annex VI of CLP therefore this proposal only seeks to confirm the classification for acute inhalation toxicity and update the classification for skin sensitisation with a subcategory. The lowest reported LC50 value is 1.2 mg/l, confirming classification with Acute Tox 4; H332 (dusts and mists) and removal of the \*. In a standard skin sensitisation study (guinea pig maximisation study), a positive response was observed in 87% of animals receiving an intradermal induction dose of 10%. This meets the criteria for classification in Category 1B.

No new relevant data are available to support classification in another hazard class, category or differentiation or to require further consideration of specific concentration limits or M-factors.

### **2.3 Current harmonised classification and labelling**

#### **2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation**

##### Classification :

Skin Sens 1; H317

Eye Irrit 2; H319

Acute Tox 4\* H332

Aquatic Acute 1 ; H400

M=10

Labelling:

GHS07, GHS09

Warning

H317, H319, H332, H400

## **2.4 Current self-classification and labelling**

### **2.4.1 Current self-classification and labelling based on the CLP Regulation criteria**

The current classification and labelling applied by the applicant and notified to the C&L Inventory is in line with the existing harmonised classification.

## **3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL**

Dichlofluanid is an active substance in the scope of Reg 528/2012. As such it is subject to the harmonised classification and labelling process in accordance with Article 36(2) of CLP. However, dichlofluanid already has an entry on Annex VI of CLP and this proposal therefore only seeks to confirm the classification for acute inhalation toxicity and update the classification for skin sensitisation with a subcategory. No relevant new data that support classification in an additional or different hazard class, category or differentiation have been made available since the classification of the substance was last considered at the EU level.

# Part B.

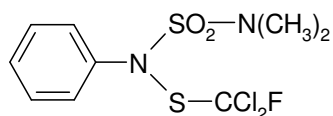
## SCIENTIFIC EVALUATION OF THE DATA

### 1 IDENTITY OF THE SUBSTANCE

#### 1.1 Name and other identifiers of the substance

**Table 4: Substance identity**

<b>EC number:</b>	214-118-7
<b>EC name:</b>	Dichlofluanid <i>N</i> -dichlorofluoromethylthio- <i>N'</i> , <i>N'</i> -dimethyl- <i>N</i> -phenylsulfamide
<b>CAS number (EC inventory):</b>	1085-98-9
<b>CAS number:</b>	1085-98-9
<b>CAS name:</b>	Methanesulfenamide, 1,1-dichloro- <i>N</i> -[(dimethylamino)sulfonyl]-1-fluoro- <i>N</i> -phenyl-
<b>IUPAC name:</b>	<i>N</i> -[(Dichlorofluoromethyl)thio]- <i>N'</i> , <i>N'</i> -dimethyl- <i>N</i> -phenylsulfamide
<b>CLP Annex VI Index number:</b>	616-006-00-7
<b>Molecular formula:</b>	C <sub>9</sub> H <sub>11</sub> C <sub>12</sub> FN <sub>2</sub> O <sub>2</sub> S <sub>2</sub>
<b>Molecular weight range:</b>	333.2

**Structural formula:****1.2 Composition of the substance****Table 5: Constituents (non-confidential information)**

Constituent	Typical concentration	Concentration range	Remarks
Dichlofluanid	98%	≥ 96%	

**Table 6: Impurities (non-confidential information)**

Impurity	Typical concentration	Concentration range	Remarks
Confidential			

There are 6 process impurities in the substance. These have been taken into consideration and are not considered to further impact on the classification proposed in this dossier. Further information on the impurities is considered to be confidential but full details are provided in the technical dossier.

**Table 7: Additives (non-confidential information)**

Additive	Function	Typical concentration	Concentration range	Remarks
Confidential				

There is 1 additive in the substance. This has been taken into consideration and is not considered to further impact on the classification proposed in this dossier. Further information on the additive is considered to be confidential but full details are provided in the technical dossier.

**1.2.1 Composition of test material**

The material used in the referenced studies was considered to be representative of the substance as identified above during the review of dichlofluanid as a biocidal active substance.



### 1.3 Physico-chemical properties

**Table 8: Summary of physico - chemical properties (ref. CAR Doc. III-A Section A3)**

Property	Value	Reference	Comment (e.g. measured or estimated)
State of the substance at 20°C and 101,3 kPa	White/yellow Solid		
Melting/freezing point	103 oC	Schneider 2001	Dir 92/69/EC A1 – Melt microscope Purity 99.4%
Boiling point	Decomposes at 120 oC	Klusacek & Krasemann 1986	OECD 113 Purity 99.9%
Relative density	1.575 at 20oC	Jungheim 2001	Dir 92/69/EC A3 Pycnometer 96%
Vapour pressure	2.15 x 10-5 Pa at 20oC 5.37 x 10-5 Pa at 25oC 3.03 x 10-3 Pa at 50oC	Treckmann, 1994	Dir 92/69/EC A4 Effusion method – vapour pressure balance 96%
Surface tension	72.75mN/m at 20 oC	Olf, 2001	OECD 115; ring method 96%
Water solubility	pH 4: 0.92 mg/l at 10 °C 1.58 mg/l at 20 °C 2.69 mg/l at 30 °C At high pH the substance rapidly hydrolyses	Schneider, 2002	OECD 105; Column elution 99.4%
Partition coefficient n-octanol/water	3.5	Schneider, 2002	OECD 117; HPLC method 99.4%
Flash point	Not applicable		
Flammability	Not flammable, not pyrophoric and does not liberate gases in hazardous amounts upon contact with water.	Heinz, 2003	Dir 92/69/EC A10, A12 and A13 Tests conducted on product Preventol A4-S <sup>(1)</sup> 89.9%
Explosive properties	Not predicted to be explosive based on a consideration of the structure.		
Self-ignition temperature	Spontaneous ignition temperature is 370 oC	Heinz, 2003	Dir 92/69/EC, A16 Tests conducted on product Preventol A4-S <sup>(1)</sup> 89.9%
Oxidising properties	Not predicted to be oxidising based on a consideration of the structure.		
Granulometry	No data		

Dissociation constant	No acidic or basic properties in water at pH 4-9	Schneider, 2002	OECD 112 99.4%
Viscosity			

<sup>(1)</sup> 90% technical dichlofluanid plus 6% silicon dioxide 1% magnesium oxide and 3% mineral oil

## **2 MANUFACTURE AND USES**

### **2.1 Manufacture**

The substance is manufactured in the EU for use as a biocidal active substance.

### **2.2 Identified uses**

Dichlofluanid is used in the EU as a biocidal active substance in wood preservatives, film preservatives and antifouling products.



### **3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES**

#### **3.1 Physical Hazards**

Not considered in this report.

### **4 HUMAN HEALTH HAZARD ASSESSMENT**

#### **4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)**

##### **4.1.1 Non-human information**

See section 4.1.3

##### **4.1.2 Human information**

None available

##### **4.1.3 Summary and discussion on Toxicokinetics**

Following oral administration in rats, dichlofluanid is rapidly and extensively absorbed from the gastrointestinal tract (70 % - 90 %), with the peak plasma concentration occurring from 1.5 to 3.0 hours post-dose. In contrast however, the single and repeated dermal application toxicodynamic studies suggest that technical dichlofluanid is poorly absorbed across the skin as indicated by no evidence of systemic toxicity. However, an *in vitro* dermal penetration study conducted using a mineral oil-based formulation, indicates that dichlofluanid in a solvent is absorbed following single dermal application. As dichlofluanid is almost completely absorbed from the gastrointestinal tract, it is predicted that it will also be well absorbed from the respiratory tract. This prediction is supported by the single inhalation exposure toxicodynamic study in rats, which provides qualitative evidence that dichlofluanid might be systemically available following exposure via this route.

Following oral dosing of radiolabelled dichlofluanid, the absorbed radioactivity is widely distributed, with erythrocytes, the liver and the thyroid gland being the sites of greatest localisation. There was some evidence that radioactivity was retained in the thyroid, suggesting the potential for accumulation at that site.

Orally administered dichlofluanid is rapidly and extensively metabolised, with no parent compound detected systemically. Initial metabolism of dichlofluanid proceeds via loss of the fluorodichloromethylsulphenyl group in reactions with cellular thiols to generate DMSA. No qualitative differences in metabolite profiles were observed between oral and intravenous administration, suggesting no significant 'first-pass' effect. It is predicted that any dichlofluanid available systemically following dermal or inhalation exposure would be similarly metabolised.

Elimination of radiolabelled dichlofluanid was rapid, with the majority of the administered radioactivity cleared during the first 48 hours. The predominant elimination route for the ring-labelled moiety is via the urine (over 90%), with a small amount eliminated via the bile. For the side-chain, the predominant route of elimination is via the urine (around 50%), with the remainder either exhaled as carbon dioxide (20-30%) or eliminated via the bile (20-30%). It is predicted that dichlofluanid metabolites produced following dermal or inhalation exposure would be similarly excreted.

(ref. CAR Doc. III-A Section A6.2)

**4.2 Acute toxicity**

**Table 9: Summary table of relevant acute inhalation toxicity studies**

Acute Inhalation		
Method	LC50	Observations and remarks
Rat (Wistar 5/sex/group) 0, 0.1, 0.5, 1.5, and 2.58 mg/l (head only) Dust aerosol (MMAD 4.8-6 µm) 4 hours (14 days post exposure) OECD 403 GLP	1.2 mg/l	Clinical signs of toxicity noted included dyspnoea, laboured breathing and lethargy at 0.5 mg/l and above. Deaths occurred at concentrations of 0.5 mg/l and above from day 0 to day-3 post exposure. No histopathological examinations were conducted, Pauluhn, J. (1988) (ref. CAR Doc. III-A Section A6.1.3)
Rat (Sprague Dawley 10/sex/group) 0, 1.09, 2.0, or 2.5 mg/l (head only) An additional group of females were exposed to 0.77 mg/l. Dust aerosol (MMAD 3.5-4.7 µm) 4 hours (14 days post exposure) US-EPA FIFRA 81-3 GLP	1.2 mg/l (m) and 1.3 mg/l (f)	Mortalities occurred in both males (0/10, 3/10, 8/10 and 10/10 at 0, 1.09, 2.0, or 2.5 mg/l respectively) and females (0/10, 4/10, 4/10, 5/10 and 9/10 at 0, 0.77, 1.09, 2.0, or 2.5 mg/l respectively), from day 0 to day 3 post exposure. Those animals dying during the study were found to have: nasal, ocular, oral and generalised facial and ventral thoracic stains; wet red or minimally firm lungs; red turbinates and ocular opacity. No treatment- related lesions were reported in surviving animals at the end of the study, Shiotsuka (1986) (ref. CAR Doc. II-A Section 3.2)

**4.2.1 Non-human information**

**4.2.1.1 Acute toxicity: oral**

Not considered in this report.

**4.2.1.2 Acute toxicity: inhalation**

The lowest 4 hour LC<sub>50</sub> (dust and mists) observed was approximately 1.2 mg/l in male and female rats.

#### **4.2.1.3 Acute toxicity: dermal**

Not considered in this report.

#### **4.2.1.4 Acute toxicity: other routes**

#### **4.2.2 Human information**

No data.

#### **4.2.3 Summary and discussion of acute toxicity**

The lowest 4 hour LC<sub>50</sub> (dust and mists) observed was approximately 1.2 mg/l in male and female rats.

#### **4.2.4 Comparison with criteria**

The values for classification as Acute Toxicity Category 4 for a dust/mist under CLP range from 1.0 – 5 mg/l. As the lowest 4 hour LC<sub>50</sub> observed in male and females rats is 1.2 mg/l, dichlofluanid should be classified as Acute Tox 4; H332 and the \* removed.

#### **4.2.5 Conclusions on classification and labelling**

<b>Acute Tox 4; H332 – Harmful if inhaled</b>
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#### **4.3 Specific target organ toxicity – single exposure (STOT SE)**

Not considered in this report.

#### **4.4 Irritation**

Not considered in this report.

#### **4.5 Corrosivity**

Not considered in this report.

## 4.6 Sensitisation

### 4.6.1 Skin sensitisation

**Table 10: Summary table of relevant skin sensitisation studies**

Species/Method	Doses	No. sensitised/total no.	Result	Reference
<p>Guinea Pig Male Pirbright 15 test and 15 control Conducted prior to guideline, but method considered to be comparable to OECD 406, GPMT Not GLP (not compulsory at the time of the study) Description, purity, and stability of the test substance were not documented.</p>	<p>Induction: Intadermal: 10% Topical: 5% Challenge: 12.5% and 25% 25% was determined to be the maximum non-irritant concentration.</p>	<p><u>12.5%</u> Test: 11/15 (73%) and 13/15 (87%) at 24 and 48 hours Negative Control: 1/15 and 0/15 at 24 and 48 hours. <u>25%</u> Test: 13/15 (87%) and 13/15 (87%) at 24 and 48 hours Negative control: 0/15 and 1/15 at 24 and 48 hours. Positive control not included.</p>	Positive	Bomhard et al (1980) (ref. CAR Doc. III-A Section A6.1.5)
<p>Guinea Pig Male Pirbright DRAIZE Test, 15 test and 15 control No guideline, Not to GLP</p>	<p>Induction: A series of intradermal injections with 0.1 % aqueous dichlofluanid Challenge: Single intradermal injection of 0.1% aq dichlofluanid</p>	<p>Test: Erythema 5/15 grade 3; 10/15 grade 4. Oedema measurement 1.1 cm Control: Erythema 15/15 grade 1 Oedema measurement 0.43 cm</p>	Positive; The study authors concluded dichlofluanid is sensitising	Bomhard,E; Loeser, E. (1980a) (ref. CAR Doc. II-A Section 3.4.1)
<p>Guinea pig (female Pirbright) 28 animals /induction concentration. Each group</p>	<p>Induction: 20 dermal applications of 1%, 3%, 10% or 30% aqueous dichlofluanid. Challenge Induction groups receiving the same induction</p>	<p>1<sup>st</sup> challenge At all challenge concentrations, mild erythema (grade 1) observed in the majority of animals receiving induction concentrations of</p>	Positive; The study authors concluded dichlofluanid is sensitising	Bomhard,E; Loeser, E. (1980b) (ref. CAR Doc. II-A Section 3.4.1)

receiving the same induction concentration was then divided into 4 groups of 7 for challenge.	concentration were divided into 4 groups of 7 and received 3%, 10%, 30% or 100% dichlofluanid respectively.	>3% (incidence not provided). 2 <sup>nd</sup> and 3 <sup>rd</sup> challenges At all challenge concentrations, positive skin reactions (grade 1) were observed in animals receiving an induction concentrations of 1%.		
KLECAK Open Epicutaneous Test				
Not guideline		Controls Positive skin reaction in 1 animal after 2nd challenge only.		
Not GLP		No further information was provided.		

#### 4.6.1.1 Non-human information

#### 4.6.1.2 Human information

Limited information is available on skin sensitisation in humans. In a patch test in 11 workers occupationally exposed to dichlofluanid, the subjects were challenged with aqueous suspensions of dichlofluanid at concentrations of up to 0.2%. No adverse skin reactions that could be clearly attributed to dichlofluanid were reported (Machemer, 1987). It should be noted that there is no evidence that aqueous dichlofluanid can cross the skin and the doses used in the study were very low.

Five brief routine health surveillance reports have been conducted between 1982 and 2003 for a few individual workers (ranging from 15-75 in the individual reports) involved in dichlofluanid manufacture. These found no evidence of adverse skin reactions that could be directly attributed to dichlofluanid. (Faul 1982, Faul 1989, Kehrig & Steffens 2003a, Kehrig and Steffens 2003b and Ochs & Heyne 2004).

(ref. CAR Doc. III-A Section A6.12 (1-6))

#### 4.6.1.3 Summary and discussion of skin sensitisation

The skin sensitisation potential of dichlofluanid has been investigated in a study that is considered to be comparable to a standard guinea pig maximisation test (GPMT) and in two non-standard guinea pig studies. Dichlofluanid gave clear positive results in the GPMT with a response in 87% of animals at challenge concentrations of 12.5% and 25% following intradermal induction at 10%. Positive skin reactions were also observed in the non-standard studies, although it is difficult to further interpret the results of these studies in line with the CLP criteria. Some human data are available from workers potentially exposed to dichlofluanid, in which no adverse skin reactions directly attributed to dichlofluanid were observed. However, these studies are of limited value due

to the small number of subjects, lack of information on exposure, low concentrations used and questions about the dermal absorption of aqueous dichlofluanid.

#### **4.6.1.4 Comparison with criteria**

A substance is classified in Category 1A where there is a  $\geq 30\%$  response in animals receiving an intradermal induction dose of  $\leq 0.1\%$  or  $\geq 60\%$  response at  $> 0.1\%$  to  $\leq 1\%$  intradermal induction dose in a GPMT.

Where there is no information to suggest that classification in Category 1A should be considered, a substance is classified in Category 1B where there is a  $\geq 30\%$  to  $<60\%$  response in animals receiving an intradermal induction dose of  $> 0.1\% \leq 1\%$  or a  $\geq 30\%$  response at  $> 1\%$  intradermal induction dose in a GPMT,

In a study that was considered to be comparable to a standard GPMT, a positive response was observed in 87% of animals receiving an intradermal induction dose of 10%, which meets the criteria for classification in Category 1B. However, it should be noted that a relatively high response (87%) was observed with an induction dose of 10% and no data are available from standard studies at lower induction concentrations. As such it could be that classification in Category 1A can not be excluded and a simple argument for retaining Category 1 could also be made (refer to the guidance document on the application of the CLP criteria section 3.4.2.2.3.2).

#### **4.6.1.5 Conclusions on classification and labelling**

<b>CLP: Skin Sensitisation 1B; H317 – May cause an allergic skin reaction</b>
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#### **4.6.2 Respiratory sensitisation**

Not considered in this report

#### **4.7 Repeated dose toxicity**

#### **4.8 Specific target organ toxicity – repeated exposure (STOT RE)**

Not considered in this report.

#### **4.9 Germ cell mutagenicity (Mutagenicity)**

Not considered in this report.

#### **4.10 Carcinogenicity**

Not considered in this report.

#### **4.11 Toxicity for reproduction**

Not considered in this report

**4.12 Other effects**

Not considered in this report

**5 ENVIRONMENTAL HAZARD ASSESSMENT**

**5.1 Degradation**

Not considered in this report.

**5.2 Environmental distribution**

Not considered in this report.

**5.3 Aquatic Bioaccumulation**

Not considered in this report.

**5.4 Aquatic toxicity**

Not considered in this report.

**5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)**

Not considered in this report.

**5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)**

Not considered in this report.



**6 OTHER INFORMATION**

NONE

## 7. REFERENCES

All references should be viewed as references to the Competent Authority Report – Doc IIIA – Study Summaries for Dichlofluanid (for use in wood preservatives – PT8) - September 2005 and Document IIA – Effects Assessment for the Active Substance – Dichlofluanid (PT8) – finalised January 2007 as prepared by the UK for the review of the active substance under Directive 98/8/EC.

Full references, as reproduced below, are also provided in the document - Directive 98/8/EC concerning the placing of biocidal products on the market - *Inclusion of active substances in Annex I to Directive 98/8/EC* - Assessment Report –DICHLOFLUANID - PT8 - November 2006

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**8. ANNEXES**

None