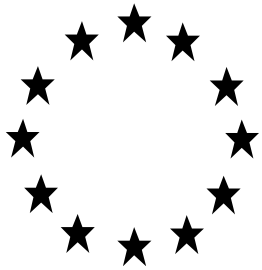
Directive 98/8/EC concerning the placing of biocidal products on the market

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

Assessment Report



DICHLOFLUANID

PT8

November 2006

Assessment report for the active substance

Dichlofluanid (PT8)

Finalised in the Standing Committee on Biocidal Products at its meeting on 28 November 2006 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 dichlofluanid as product-type 8 (Wood Preservatives), 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.

Dichlofluanid (CAS no. 1085-98-9) was notified as an existing active substance, by Lanxess Deutschland GmbH, D-51360 Leverkusen, Germany (formerly part of Bayer Chemicals AG), hereafter referred to as the applicant, in Product Type 8 (Wood Preservatives) for industrial, professional and amateur use.

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 10 of that Regulation, the Commission designated the United Kingdom (UK) as Rapporteur Member State to carry out the assessment of dichlofluanid on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for dichlofluanid as an active substance in Product Type 8 (Wood Preservatives) was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 29 March 2004, the UK competent authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation, taking into account the supported uses, and confirmed the acceptance of the dossier on 6 September 2004.

On 4 October 2004, in accordance with Article 9(3) of Regulation 2032/2003, the applicant sent the summary dossier to the Commission and the Member States.

On 1 September 2005, the Rapporteur Member State submitted, in accordance with the provisions of Article 11(2) of Directive 98/8/EC and Article 10(5) of Regulation 2032/2003, to the Commission and the applicant a copy of the evaluation, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 13 September 2006. The competent authority report included a recommendation for the inclusion of dichlofluanid in Annex I to the Directive for PT 8.

In accordance with Article 12 of Regulation (EC) 2032/2003, the Commission made the competent authority report publicly available by electronic means on 20 December 2005. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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 OJ L 307, 24.11.2003, p. 1

In order to review the competent authority report and the comments received on it, the European Chemicals Bureau of the European Commission organised consultations of technical experts from all Member States (peer review). 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 dichlofluanid in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 28 November 2006.

The present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 28 November 2006. This assessment report should be read in conjunction with Documents I and II of the competent authority report.

1.2 Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include dichlofluanid in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation and registration in Member States of individual biocidal products in product-type 8 that contain dichlofluanid. 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 the 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 wood preservatives containing dichlofluanid 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), and

iii. the common principles laid down in Annex VI to Directive 98/8/EC, for each wood preservative containing dichlofluanid.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix III). Extension of the use pattern beyond those described will require an evaluation at Member State level in order to establish

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

whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI of Directive 98/8/EC.

2 OVERALL SUMMARY AND CONCLUSIONS

2.1 Identity, Intended Uses, Efficacy and Classification of the Active Substance

2.1.1 Identity & Analysis

The main identification characteristics and the physico-chemical properties of dichlofluanid are given in Appendix I and the 'Confidential Annex' of the competent authority report. The evaluation has established that for the active substance notified by Bayer Chemicals AG/Lanxess Deutschland GmbH none of the manufacturing impurities are considered to be of potential concern. However, N,N-Dimethyl-N'-phenylsulfamide (DMSA) is a precursor to the formation of dichlofluanid, an impurity in the technical dichlofluanid and a metabolite formed from the breakdown of dichlofluanid. As it is formed from the degradation of dichlofluanid in the environment it is considered in the environmental risk assessment for the active substance. It is not an issue for the human health risk assessment as the *in vivo* data provide information on the effects from dichlofluanid and any metabolites that are formed.

The methods of analysis for the active substance as manufactured, and for the determination of impurities, have been validated. The methods for analysis in environmental matrices, as appropriate for the areas of use assessed, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

2.1.2 Intended Uses

Dichlofluanid has been evaluated for its use in wood preservation (product-type 8) up to Hazard Class 3 (i.e. wood which is not covered and not in contact with ground, but exposed to weather or frequent wetting). It is applied in solvent-based product formulations either in primers or incorporated in low binder-containing paints (e.g. glazes). Products can be used for:

- the pre-treatment of timber (dipping and automated enclosed spraying by industrial/professional users); and

- the protective treatment of wood *in situ* by brush application (both professional and amateur users).

Dichlofluanid is not recommended for treatment of wood inside housing areas (with the exception of window frames and external doors, which will usually be treated on or before installation) or for spraying manually in open systems.

The guide formulation for a biocidal product submitted by the applicant contains 0.55% w/w dichlofluanid. A ready-to-use formulation containing up to 0.7 % w/w dichlofluanid has been considered, because the applicant believes that there is a market trend towards applying less product and/or making fewer applications to the timber. Therefore, to achieve the required retention of dichlofluanid in the wood (1.1 g/m^2 or 90 g/m^3), a more concentrated product is needed. In addition the use of a product concentrate containing 10 % w/w dichlofluanid, which would be diluted down to the concentration of the ready-to-use products before application, has also been considered for industrial/professional use (dipping and automated enclosed spraying).

As the use of a product containing 0.7% w/w dichlofluanid, rather than 0.55 % w/w, would result in potentially higher exposure, the higher % w/w value has been used in both the human and environmental risk assessments (where applicable). Once applied to the wood, the same retention in the wood is achieved in both cases so efficacy and environmental risk assessments relying on leaching are unaffected.

2.1.3 Efficacy

Data on the active substance, dichlofluanid, and the biocidal product (containing 0.55% w/w dichlofluanid) have demonstrated sufficient efficacy against wood-staining fungi (blue-staining fungi) for inclusion on to Annex I to be recommended. Dichlofluanid acts by targeting a number of metabolic processes, and thus the development of resistance in the target organism is considered to be of low risk.

2.1.4 Classification

On the basis of a review of the data submitted, it is suggested that the current classification of dichlofluanid on Annex I to Directive 67/548/EEC should be modified, so as to delete the R53 (MAY CAUSE LONG-TERM ADVERSE EFFECTS IN THE AQUATIC ENVIRONMENT). This proposal is based on the rapid hydrolysis of dichlofluanid in water and the low acute and long-term toxicity to aquatic organisms of the resulting degradation product DMSA, as well as the lack of bioconcentration of both dichlofluanid and DMSA. The proposed classification for dichlofluanid, given in Table 1, should be discussed further at the EU Technical Committee on Classification & Labelling.

Table 1 : Proposed classification for dichlofluanid

Classification	Proposed classification for dichlofluanid following evaluation
Class of danger	Xn: Harmful; N: Dangerous for the environment.
R-phrases	R20: Harmful by inhalation; R36: Irritating to eyes; R43: May cause sensitisation by skin contact; R50: Very toxic to aquatic organisms.

Based on the proposed classification for dichlofluanid, and information available on the co-formulants, the classification of the representative solvent-based product containing dichlofluanid (guide formulation JJT 3581) can be determined. The proposed classification for the product is given in Table 2.

Table 2 : Proposed classification for representative solvent-based ready-for-use product

Classification	Proposed classification for representative product following evaluation
Class of danger	Xn: Harmful.
R-phrases	R65: Harmful: may cause lung damage if swallowed; R66: Repeated exposure may cause skin dryness or cracking.
Additional labelling	“Contains dichlofluanid. May produce an allergic reaction.”

However until the classification of dichlofluanid on Annex I of Directive 67/548/EEC is amended, the solvent-based product should be classified as given in Table 3.

Table 3 : Current classification for representative solvent-based ready-for-use product

Classification	Current classification for representative product
Class of danger	Xn: Harmful.
R-phrases	R 52/53, Harmful to aquatic organisms; May cause long-term adverse effects in the aquatic environment; R65: Harmful: may cause lung damage if swallowed; R66: Repeated exposure may cause skin dryness or cracking.
Additional labelling	"Contains dichlofluanid. May produce an allergic reaction."

2.2 Summary of the Risk Assessment

2.2.1 Human Health Risk Assessment

2.2.1.1 Toxicology hazard summary

The potential human health effects of dichlofluanid have been well investigated, almost exclusively in experimental animals. Dichlofluanid is of low acute toxicity by the oral and dermal routes of exposure, but has moderate acute toxicity by the inhalation route.

It is not a skin irritant, but is an eye irritant. There is evidence that dichlofluanid can cause some respiratory tract irritation; however the strength of evidence does not meet the EU criteria for classification for respiratory tract irritation. Dichlofluanid is a skin sensitiser, but there is insufficient information to determine whether or not it can cause respiratory sensitisation/occupational asthma.

Following repeated oral administration of dichlofluanid, the most prominent finding was fluorosis caused by the release of fluoride from the dichlofluanid molecule during its metabolism. This resulted in skeletal osteosclerosis, observed in lifetime dietary studies in both rats and mice. Chronic nephropathy was also observed following repeated oral administration, but in dogs only. The mode of action for the nephropathy is uncertain and possible explanations include direct nephrotoxicity of the active substance or a secondary consequence of elevated systemic fluoride levels. Dichlofluanid did not cause systemic toxicity following repeated dermal application. No repeated inhalation studies have been conducted; from the overall toxicological profile it is considered reasonable to predict the consequences of repeated inhalation exposure by extrapolating from repeated oral dosing studies.

The weight of evidence from a number of well-conducted *in vitro* and *in vivo* genotoxicity studies suggests that it is not genotoxic *in vivo*. In terms of carcinogenicity, dichlofluanid induced thyroid tumours in rats at high doses, but by a mechanism not considered to be relevant for human health. No increase in tumour incidence was observed in mice. Overall, dichlofluanid does not show any carcinogenic potential of relevance to human health.

In experimental animal studies dichlofluanid did not affect fertility and did not cause developmental toxicity. The evidence suggests that this substance does not possess significant potential with respect to toxicity for reproduction.

2.2.1.2 Critical end points

2.2.1.2.1 Single exposure

The results of single inhalation exposure studies support classification of dichlofluanid for acute toxicity by the inhalation route of exposure. However, as the representative solvent-based product contains less than 25 % w/w dichlofluanid, and no other co-formulants are classified for this endpoint, the product will not attract this classification, and this endpoint does not need to be considered further in the risk characterisation. However the product does contain a co-formulant at a concentration that meets the criteria for classification for an aspiration hazard and so must be classified accordingly.

Dichlofluanid exhibits the potential to produce eye irritation on direct contact with the eyes. In animal studies, dichlofluanid met the criteria for classification as an eye irritant.

However, as the representative solvent-based product contains less than 20 % w/w dichlofluanid and no other co-formulants classified for this endpoint, the product will not attract this classification. Hence this endpoint does not need to be considered further in the risk characterisation.

2.2.1.2.2 Sensitisation

Positive findings from guinea pig sensitisation studies indicate that dichlofluanid has skin sensitisation potential. However, as the representative solvent-based product contains less than 1 % w/w dichlofluanid, and no other co-formulants classified for this endpoint, the product will not attract this classification. Hence this endpoint does not need to be considered further in the risk characterisation.

2.2.1.2.3 Repeated dose

The relevant information for risk characterisation for repeated exposure to dichlofluanid comes largely from studies conducted in rats and dogs. These studies indicate two critical effects: skeletal osteosclerosis and chronic nephropathy, observed in rats and dogs respectively.

The toxicokinetic studies show that fluoride is released from the parent molecule. The bones and teeth will take up any bioavailable fluoride if the body burden is sufficiently high and exposure is sufficiently prolonged. If the degree of such uptake is excessive, it can lead to skeletal osteosclerosis. This explains the mechanism behind the observed skeletal osteosclerosis seen in rodents. It is possible that the kidney toxicity seen in dogs is also a consequence of the excess fluoride, especially as fluoride is excreted via the kidneys. However, there is no direct information to confirm this possibility. Given this uncertainty, the kidney changes should be considered as a separate effect.

In the lifetime oral study in rats, skeletal osteosclerosis was observed at all doses; therefore it was not possible to identify a NOAEL for this effect. A LOAEL of 9.4-13.5 mg/kg/day was established, which was at the lowest dose used.

In humans, prolonged environmental exposure to high levels of fluoride causes adverse dental changes as well as skeletal changes. There are human data that indicate that intakes above 0.05 mg fluoride/kg/day will cause moderate dental fluorosis; and human population studies indicate that skeletal fluorosis occurs following prolonged environmental exposure at intakes of around 0.1-0.23 mg fluoride/kg/day. Therefore elevated fluoride levels are of concern for human health.

The risk to health posed by dichlofluanid in this respect has been assessed by considering the impact that exposure to dichlofluanid could have on the body burden of fluoride in humans.

Therefore the human health risk characterisation has been conducted by adding the maximum potential systemic fluoride contribution from dichlofluanid to the total human intake of fluoride from the environment and directly comparing this sum to the threshold for fluorosis in the human population. In the UK, the Total Dietary Survey found the average adult dietary intake to be around 0.02 mg fluoride/kg/day and that for children aged 4-6 years to be 0.03 mg fluoride/kg/day. These values were used in the risk characterisation as the environmental intake values. The threshold for fluorosis in humans for moderate dental fluorosis is 0.05 mg fluoride/kg/day. The maximum systemic fluoride dose arising from dichlofluanid exposure can be estimated from the worst-case repeated exposure scenario, assuming 5.7% by weight of fluoride and 100% release of fluoride from dichlofluanid during metabolism.

In the 1-year oral study in dogs, a NOAEL of 2.5 mg/kg/day was identified for minimal to moderate chronic nephropathy. In the 90-day oral study in dogs there was no clear evidence of nephropathy, with the study providing a NOAEL of 20 mg/kg/day. Minor clinical chemistry changes, possibly suggestive of the onset of nephrotoxicity, and mild liver toxicity were observed at 35 mg/kg/day, the highest dose used. The mode of action for the nephropathy is uncertain and possible explanations include direct nephrotoxicity of the active substance or a secondary consequence of elevated systemic fluoride levels. In either case, dichlofluanid-mediated nephrotoxicity in dogs is potentially relevant for human health and has therefore been considered in the risk characterisation.

The NOAEL of 2.5 mg/kg/day is proposed for use in the risk characterisation of nephrotoxicity in prolonged exposure scenarios. For shorter duration scenarios, a NOAEL of 20 mg/kg/day for mild kidney and liver effects is available from a 90-day dog study. However it is noted that this value of 20 mg/kg/day is taken from a relatively long exposure period in dogs, equivalent to years of exposure in humans.

The representative solvent-based product contains co-formulants, at a concentration that meets the criteria for classification for skin dryness and cracking on repeated exposure.

2.2.1.3 Uncertainties

2.2.1.3.1 Dermal Absorption Values Used in the Risk Assessment

There are no studies on the dermal absorption of the active substance. In the absence of a study, it is usual practice to consider the use of a default value. According to the NONS/ESR/Biocides Technical Guidance Document default values can be selected based on the physico-chemical properties of a substance. In the case of dichlofluanid, both the molecular weight (333.2) and log Pow (3.5) indicate that 100% absorption should be taken as the default. However, there is additional, toxicokinetic and toxicodynamic information that

should be taken into consideration before deciding which default dermal absorption value should be used.

According to toxicokinetics studies, dichlofluanid is well absorbed (70-90%) from the GI tract, following single oral exposure. In the shortest duration oral repeat dose study available (Lorke, 1964) dichlofluanid causes systemic toxicity in rats at doses of around 150 mg/kg/day for 120 days, with a NOAEL of 50 mg/kg/day. In contrast, in the only repeat dose dermal study available, no evidence of systemic toxicity was observed following repeated dermal application in rats for 28 days, at the highest dose of 1000 mg/kg/day. If dermal penetration was similar to oral absorption, that is around 70-90%, it is anticipated that, taking into account the difference in study durations, some systemic toxicity would have been observed in this study. The absence of systemic toxicity following repeated dermal application, when compared to exposure via the oral route, argues strongly that a default of 100 % is not appropriate for the dermal penetration and that the dermal penetration value is less than 70-90%.

If the oral NOAEL value and the dermal highest dose tested showing no toxicity are scaled up or down, to allow for differences in duration of the oral and dermal studies, the dermal highest dose tested showing no toxicity is one fifth of the oral NOAEL. This suggests that dermal absorption may be at least one fifth of the oral absorption, but a specific value cannot be determined.

However a dermal absorption study, conducted on a mineral oil-based formulation containing 0.55 % w/w dichlofluanid, was submitted. In this study, around 37.37 % of the dichlofluanid in this formulation reached the receptor fluid, with a further 22.48 % retained within the stratum corneum and 8.09 % below the stratum corneum. There are differing views, which were discussed at Biocides Technical Meetings (TMI06, TMII06 and TMIII06), over how to take account of material retained within the stratum corneum in deriving an overall dermal absorption value. If all the material retained in the stratum corneum was considered as part of the overall dermal absorption value this would result in unacceptable MOEs for some exposure scenarios. In addition, it would be unrealistic to presume that all of the material lodged within the stratum corneum would be available systemically because some will be lost via the natural process of sloughing (loss of dead skin cells).

It is considered that this *in vitro* study has been well conducted, with the skin exposed to the test substance for a 24-hour period. The amount of test substance reaching the receptor fluid has also been measured for the 24-hour period, showing a maximum absorption rate occurring between 2 and 4 hours post-administration, and then declining steadily to 24 hours post-administration. At the end of this study (i.e. 24 hours post-administration) it is considered that only test substance that has penetrated the stratum corneum will be systemically available and so contribute to the daily body burden. Consequently, for the solvent-based product, the overall dermal absorption value for dichlofluanid is 37.37 + 8.09 % = 45.46 %. As the presence of solvent in the product tested might be expected to enhance the dermal absorption of the dichlofluanid, in the absence of solvent the dermal absorption of the active substance would be expected to be lower than this value. However, as a worst-case, it was agreed to use a dermal absorption of 45.46 % for the risk characterisation of dichlofluanid in all dermal exposure scenarios irrespective of whether solvent is present or has evaporated off.

However, the representative solvent-based product contains co-formulants that may cause skin cracking. Should this occur, dermal absorption may be enhanced.

2.2.1.3.2 Inter- and Intra-species Variability

In considering fluorosis, human data on the health consequences of fluoride levels in the body provide the basis for the risk characterisation for this effect and there is no need for extrapolation from experimental animal data. Also, inter-individual (human to human) variability is already accommodated within such data. Therefore there is no need to take further account of potential inter- or intra-species variability in the risk characterisation for adults.

In considering chronic nephropathy, extrapolation from animal to human data is necessary to conduct a risk characterisation for this effect. However, there is no information available to identify the relative sensitivities of dogs and humans in relation to the ability of dichlofluanid to produce chronic nephropathy. Similarly, there are no data to reliably inform on the potential for inter-individual variability in susceptibility to this effect. Therefore standard default factors to account for potential inter-species (human compared with dog) and intra-species (human to human) variability need to be included in the risk characterisation.

2.2.1.3.3 Route to Route Extrapolation

There are no repeated inhalation studies available for systemic toxicity. However, from the toxicokinetic studies there appears to be no significant first-pass metabolism. Therefore one would expect similar toxicokinetic, and hence toxicodynamic, profiles for dichlofluanid following both oral and inhalation exposures. Hence oral to inhalation extrapolation for systemic effects is considered valid for the risk characterisation of repeated inhalation exposure scenarios.

Dermal data are available that indicate that dichlofluanid does not cause systemic toxicity. However this information is from a 28-day rat study. For longer-term studies it is necessary to extrapolate from oral data.

2.2.1.3.4 Reference values

For human health risk assessment concerning primary exposure to dichlofluanid the following toxicological reference values are derived with respect to nephrotoxicity:

The $AOEL_{long\text{-}term}$ is derived as 0.025 mg/kg/day on the basis of the NOAEL from the 1-year oral dog study including a safety factor of 100.

The $AOEL_{short\text{-}term}$ is derived as 0.2 mg/kg/day on the basis of the NOAEL from the 90-day oral dog study including a safety factor of 100.

For risk assessment with respect to fluorosis, the maximum fluoride intake from dichlofluanid exposure is weighed against the average environmental fluoride intake. An ADI for dichlofluanid of 0.35 mg/kg/day was determined based on human studies.

2.2.1.4 Exposure from Use of Product

Exposure during the production and formulation of dichlofluanid should be addressed under other EU legislation (e.g. Directive 98/24/EC[4]) and not repeated under Directive 98/8/EC. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for dichlofluanid which is an existing biocidal active substance within the EU.

Exposure assessments have been carried out on a solvent-based 'ready-to-use' guide formulation containing a maximum of 0.7% w/w dichlofluanid. Both primary and secondary exposures were considered. The primary exposure scenarios considered in the human risk assessment are:

- mixing, loading (i.e. dilution of and/or transfer of concentrate liquids) and application by dipping (including automated enclosed spraying) of wooden articles (industrial and professional users);
- handling of wet treated wood (industrial and professional users);
- cleaning out the dipping tank after use (industrial and professional users); and
- application by brush to wood (professional and amateur users).

whilst the secondary exposure scenarios reviewed are:

- adults sanding treated wood (professionals and amateurs);
- adults cleaning work clothes at home;
- children playing on treated wooden playground structures outdoors;
- infants playing on treated wooden playground structures and making hand-to-mouth contact; and
- infants chewing treated wood off-cuts.

Models and assumptions were taken from the Technical Notes for Guidance on Human Exposure to Biocidal Products (2002), as revised by User Guidance version 1 (2002).

Primary Exposure

The potential exposure of an operator through ingestion is considered negligible and has therefore not been pursued further. Operator exposure through inhalation is low (due to the low vapour pressure of dichlofluanid) but has been included in the exposure assessments. The majority of the exposure occurs via dermal penetration. A value of 45.46% for dermal penetration of dichlofluanid from solvent-based product data was used, and the body weight of the operator was taken as 60 kg.

4 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work. OJ L 131, 5.5.1998, p. 11–23

Nephrotoxicity

For primary exposure, the worst-case systemic doses of dichlofluanid estimated were 0.0288 mg/kg/day for industrial/professional mixing, loading and dipping (including automated enclosed spraying); 0.0115 mg/kg/day for industrial/professional cleaning of the dipping tank (without RPE); 0.0131 mg/kg/day for professional application by brush; and 0.0919 mg/kg/day for amateur application by brush, without wearing gloves. For industrial/professional users handling treated wet timber, exposure was 0.0117 mg/kg/day.

Fluorosis

From the worst-case systemic dose of 0.0288 mg dichlofluanid/kg/day, and given that dichlofluanid contains 5.7 % w/w fluoride, this corresponds to a maximum fluoride intake of:

0.0288/100 x 5.7 = 0.0016 mg fluoride/kg/day

Adding this to an average environmental fluoride intake of 0.02 mg/kg/day for adults (from the UK Total Dietary Survey) gives a worst-case fluoride body burden of 0.022 mg/kg/day.

Secondary Exposure

Secondary exposure may occur soon after application of a product with a short exposure period (acute phase), alternatively, exposure may be long term and repeated (chronic phase). This secondary exposure may result from professional and amateur applications. All of the secondary exposure scenarios presented involve skin contact, although in practice persons handling treated timber in large amounts would be expected to wear gloves to protect their hands from splinters and abrasions. Treated wood is not placed on the market until the timber is dry and in the secondary assessments a dermal absorption below 45.46 % would be anticipated as the solvent in the formulation is expected to have evaporated and technical dichlofluanid has a low water solubility. However as worst-case a dermal absorption value of 45.46 % was used. Similarly, in assessing exposure from washing contaminated clothing, it is considered that the solvent will have evaporated from the clothing, but the worst-case dermal absorption value of 45.46 % was used. Infants may have dermal contact with contaminated objects and then make hand-to-mouth contact. Also, infants may chew treated wood.

Nephrotoxicity

Estimates of secondary exposure indicated a worst-case systemic dose of 0.0236 mg/kg/day for an infant chewing treated wood off-cuts (acute phase) and 0.0128 mg/kg/day for an infant playing on treated wooden playground structures and then making hand-to-mouth contact (chronic phase).

Fluorosis

From the worst-case systemic dose (chronic phase) of 0.0128 mg dichlofluanid/kg/day, and given that dichlofluanid contains 5.7 % w/w fluoride, this corresponds to a maximum fluoride intake of:

0.0128/100 x 5.7 = 0.0007 mg fluoride/kg/day

Adding this to an average environmental fluoride intake of 0.03 mg/kg/day for infants (from the UK Total Dietary Survey) gives a worst-case fluoride body burden of 0.0307 mg/kg/day.

2.2.1.5 Summary of risk characterisation for humans

The industrial/ professional scenario with the highest potential for primary human exposure is dipping of timber (including a mixing/loading phase for the product concentrate); and for this scenario the wearing of suitable protective gloves (new at the start of each daily dipping session), footwear and impermeable coverall, plus for mixing/loading, eye/face protection, have been taken into account (see Table 1). For nephrotoxicity, a MOE (margin of exposure) of 87 is estimated (corresponding to an exposure of about 115 % of the AOEL), which is below the 'default' level of acceptability. The 'default' level, a MOE of 100, is based on factors of 10 to allow for both inter- and intra-species variability. However, it is noted that the LOAEL for nephrotoxicity is five times higher than the NOAEL and that effects at the LOAEL were not severe. This provides some reassurance.

Table 1: Summary of human health risk assessment for primary exposures to dichlofluanid

	MOE	Exposure ÷ AOEL
Industrial/Professional users		
Mixing + loading	8333	0.012
Mixing + loading, dipping, automated enclosed spraying	87	1.152
Handling of treated wet wood	214	0.468
Cleaning out dipping tank (without RPE)	217	0.46
Cleaning out dipping tank (with RPE)	221	0.452
Brushing/painting	191	0.524
Amateur users		
Brushing/painting (with gloves)	356	0.281
Brushing/painting (no gloves)	218	0.4595

The indicative exposure data used in the exposure calculations are for manual dipping, where a high degree of exposure can be expected. It was considered that the use of dichlofluanid in the manual dipping of wooden articles would not be acceptable for the representative solvent-based formulation submitted. For automated dipping processes, or where the timber is lowered and raised mechanically in and out of the dipping tank and drained, operator exposure should be considerably lower than for the manual process. Taking these points into account, it was considered that the use of dichlofluanid for dipping wooden articles by automated/mechanical processes is acceptable. For amateur brushing of timber, with and without the wearing of gloves, the MOEs for nephrotoxicity are estimated to be 356 (28 % of the AOEL) and 218 (46 % of the AOEL) respectively, and these are acceptable.

When workers are using the product a high standard of technical and organisational protection measures must be maintained. Workers should wear suitable protective clothing, including gloves and footwear. For dipping (including mixing/loading operations) and cleaning out the dipping tank, considerable contamination of the operator can be anticipated thus warranting a higher degree of protection than typical work clothing. For the purpose of this risk assessment it is assumed that impermeable coveralls will be worn. Also, to reduce exposure via the hands, operators would be required to wear new protective gloves at the start of each daily dipping session. This requirement has been previously accepted by users for

other wood preservative products, and can be readily assessed by inspection to ensure compliance. It should be incorporated into the product labels.

For risk assessment at the workplace, the use of new gloves at the start of each new day of automated dipping was taken into account, to provide the necessary chemical protection to the operator. However, as for all chemicals, recognition should be given to improving the risk situation by technical and organisational measures. Experience from some Member States suggests that, in some small wood preservative enterprises, operators wear textile or leather gloves when handling timber during the dipping process to protect their hands against splinters/roughness, and from which no chemical protection is expected. It should be emphasised that if protective gloves are necessary they must be compatible with all aspects of the work to be done, and manufactured to an appropriate standard. Standards for protective gloves are prescribed under Directive 89/686/EEC, and subsequent EU legislation. Protective gloves combining the qualities of both protection against chemicals and protection against mechanical hazards (such as wood splinters and roughness) are available on the market. Alternatively, it may also be possible for operators to wear two pairs of gloves; one pair to protect against chemical hazard and one pair to protect against mechanical hazard.

When cleaning out the dipping tank, suitable RPE is recommended.

Operators must not eat, drink or smoke, they must avoid product contact with eyes and skin, and they must not intentionally breathe vapour from the product. The product should only be used in well-ventilated areas and maximum ventilation should be maintained during drying of treated timber. Unprotected persons, children, animals, domestic pets and wildlife must be kept away from the product and from freshly treated timber until surfaces are dry. Any surplus/contaminated product and its container must be disposed of in a safe and appropriate way.

Secondary exposure is highest for infants chewing treated wood off-cuts (acute phase) and infants playing on treated wooden structures and making hand-to-mouth contact (chronic phase). However, the MOEs of 847 and 195 respectively for nephrotoxicity are acceptable.

Comparing the worst-case body burdens of fluoride for adults and children to the NOAEL for moderate dental fluorosis of 0.05 mg fluoride/kg/day indicates that fluoride, released from dichlofluanid, is unlikely to pose a significant concern for human health. Therefore risk characterisation of other exposure scenarios where lower body burdens of dichlofluanid are anticipated is not necessary. It is considered that the potential contribution of dichlofluanid to the total intake of fluoride is not of concern for the primary or secondary exposure of either adults or children.

Combined exposure

It is considered that none of the primary and secondary exposure scenarios, other than possibly professional product painting and handling of dried treated timber (MOE = 172) or cleaning out the dipping tank and handling of dried treated timber (MOE = 197), realistically warrant combination to provide a combined dose of dichlofluanid, since the other events are unlikely to happen to one person on the same day.

Other effects

It is considered that classification of the product for an aspiration hazard is of concern only for ingestion by children, however the product should be labelled with a warning to keep it out of the reach of children. Member States may need to consider appropriate warning labels and, as necessary, child-resistant closures, when they evaluate genuine products for authorisation. However, no risk mitigation measures were further considered here, as the product submitted is a representative, rather than an actual, product.

The potential for the product to cause dryness and cracking of the skin on repeated exposure is not believed to be a concern for amateur users since they are unlikely to use the product frequently enough. Industrial and professional workers may use the product regularly but their skin exposure will be minimised by the use of coveralls and gloves. It is considered that this is acceptable. The potential for the product to cause dryness and cracking of the skin on repeated exposure is not believed to be a concern for secondary exposure.

2.2.2 Environmental Risk Assessment

2.2.2.1 Effects Assessment

Dichlofluanid hydrolyses rapidly to DMSA (N,N-dimethyl-N'-phenylsulfamide). It is also inherently biodegradable and, in biologically active soils, is degraded to DMSA with a half-life of less than one day (DT_{50} < 1 day).

Leaching studies in soil showed that dichlofluanid was not mobile but was rapidly degraded under the conditions of the available studies, whereas DMSA was shown to be mobile and susceptible to degradation with time. Dichlofluanid and DMSA are unlikely to bioaccumulate.

The very low vapour pressure (2.15×10^{-5} Pa at 20 °C) indicates that dichlofluanid has a low tendency to volatilise, therefore air has not been considered as a compartment of concern.

Dichlofluanid is extremely toxic to aquatic organisms, whereas DMSA has a low toxicity. A short term toxicity test submitted for the terrestrial toxicity endpoint demonstrates that dichlofluanid has a relatively low toxicity to earthworms (see Appendix II).

2.2.2.2 Exposure Assessment

The OECD ESD guidance available is limited to local exposure calculations for wood preservative life-cycle stages of 'product application' and 'wood in-service' only. Therefore the assessment has determined local concentrations for these life-cycle stages. No determination of the regional concentrations has been made, since the wood preservative uses outlined are not considered to be of sufficiently large scale and there are no realistic or robust methods available to predict regional concentrations for wood preservatives. Consideration of regional concentrations and additional life-cycle stages has been deferred to the Member State assessment at the product authorisation stage.

2.2.2.3 Risk Characterisation

2.2.2.3.1 Aquatic Compartment

There is no unacceptable risk to sewage treatment plants (STPs) from industrial applications and in-service leaching.

For both industrial applications investigated the initial PEC:PNEC values were < 1 for surface water and are acceptable. The risk of exposure to DMSA, which is expected to be the major component in the environment, was also shown to be acceptable for the industrial application scenarios investigated.

For in-service leaching the risk to surface waters was acceptable for the noise barrier scenario for both the short and long-term (15 yr) assessments. However, the risk was unacceptable for both the in-service leaching and *in situ* application stages for the bridge over a pond scenario. For this reason, the applicant's proposal of label instructions that prevent applications to timber where direct losses to water are possible was endorsed.

A sediment risk assessment was conducted for DMSA following a request made at TMI06. The assessment was carried out despite the physico-chemical properties not meeting the trigger threshold criteria set out in the TGD. The assessment used a predicted PNEC value

based on the equilibrium partition method as no spiked sediment data were available for DMSA. The assessment demonstrated an unacceptable risk only for the long-term assessment in the bridge over a pond scenario. This was due to the lack of degradation being accounted for in the calculations. However, given the proposed restrictions on applications of dichlofluanid to timber where direct losses to water can occur, no further refinements were considered necessary.

2.2.2.3.2 Terrestrial compartment

The hazard profile for dichlofluanid has shown that it degrades rapidly in soil to DMSA. Therefore an estimate of the risks posed to soil by DMSA has been made, based on a worst-case situation. A worst-case PEC has been estimated by assuming all the dichlofluanid is metabolised to DMSA, whilst a PNEC has been predicted using the equilibrium partition method (as no toxicity studies on DMSA for the soil compartment were submitted). Data have been presented to show that DMSA would be removed from the soil compartment through either degradation to bound residues (under aerobic conditions) or via leaching down the soil column.

The short (30 d) and long-term (20 years) risks posed to the local soil compartment within the storage areas of industrial wood treatment sites were not acceptable for dichlofluanid (PEC:PNEC values 86.41 and 21050). The scenario assumes that all freshly treated timber is stored on-site for 15 days on bare earth with no degradation. Although it is considered that dichlofluanid will degrade sufficiently during this time (half-life of 2 days at 12^{o}C), the risks from DMSA have also been shown to be unacceptable (PEC:PNEC values 8.35 and 8.13). Therefore, it is proposed that this risk is mitigated by restricting the storage of industrial treated timber to areas of impermeable hard standing (usually concrete with an impermeable barrier beneath it) so as to prevent direct losses to soil, and allow the recovery of the losses for recycling or appropriate disposal. This is currently considered good practice by the UK wood preservative industry.

The PEC:PNEC values produced for dichlofluanid as a result of the *in situ* application and short and long-term in-service leaching scenarios for wood out of ground contact ranged from 0.89 to 43.49. These data demonstrate that in the short-term, acute exposures of the soil compartment to dichlofluanid may be unacceptable. However, this effect is restricted to the immediate environment and would not pose any risk to the wider environment especially considering the active substance is immobile and rapidly degradable. The longer-term assessments for dichlofluanid are considered extremely unrealistic due to the rapid degradation to DMSA in soil (half-life ~ 2 days) and the semi-continuous nature of the emissions from leaching. For the long-term assessments with DMSA the PEC:PNEC values remained > 1 for all scenarios considered, unless removal to groundwater was accounted for by increasing the depth of the soil (to 1 m), which then reduced the PEC:PNEC to < 1 for the noise barrier only

- At the 23rd CA meeting it was agreed to use a distance of 50 cm for the determination of the PEC:PNEC ration rather than the 10 cm previously used. It was also agreed that if the PEC:PNEC ratio was greater than 1 then this should trigger risk mitigation measures being required to achieve a PEC/PNEC ratio equal to or below 1 at the product authorisation stage. As this is the case for Dichlofluanid, appropriate risk mitigation measures to protect the soil compartment are required.

It is accepted that this approach is not scientifically robust as the impact on the wider environment, through removal to deeper substrate and groundwater, is not taken into account.

For DMSA, removal to groundwater has been predicted using standard FOCUS modelling techniques established for the Plant Protection Products Directive 91/414/EC. The levels predicted are considered acceptable on the grounds that they are either < 0.1 µg/l (drinking water limit for pesticides) or are only a fraction of the ADI when consumed as part of the daily diet.

Overall, it is considered that the risk to soil presented by dichlofluanid and DMSA should be viewed in terms of the long-term impacts on the environment as a whole. The use of wood preservatives *in situ* and subsequent leaching from treated surfaces will result in some very localised contamination of the soil environment. However, it was agreed that the impact of the active substance (or metabolite(s)), based upon the fate and behaviour data submitted by the applicant should then be used to inform the 'bigger picture' as far as environmental impact is concerned. Where a substance, such as dichlofluanid, is shown to remain adsorbed to the soil before rapidly degrading to a metabolite, any risk posed to the immediate soil environment will not be of concern because any risk will be 'contained' and will not affect the wider environment. In addition it should be noted that dichlofluanid has been extensively used as an agricultural pesticide, and applied to a wide range of crops, with no adverse effects on soil being reported.

The metabolite, DMSA, cannot be considered to be contained as this has been shown to have mobile properties and modelling showing potential exposure to groundwater demonstrates this further. Therefore, mobility needs to be taken into account when defining the volume of soil likely to be contaminated. Where an unacceptable risk remains, again this is 'contained' and restricted to a very small portion of the soil compartment and is therefore extremely unlikely to have impact on wider soil communities. Furthermore, the levels predicted in groundwater (based on worst-case assumptions) would not be of concern environmentally (since DMSA is considered acceptable in all flowing water scenarios) or for human health.

The conclusions of the assessment are that:

- **For *in situ* and in-service use**
    - Any risks posed from both the short and long-term use are contained and have no influence on the wider environment.
    - The use of wood preservative products containing dichlofluanid at up to 0.7 % w/w (with a retention of 1.1 g dichlofluanid/m^2 timber) for outdoor structures out of ground contact are acceptable.
- **For industrial applications (Dipping and Automated spray)**
    - In the absence of specific data to refine the industrial storage exposure scenarios, and because the levels predicted with long-term use were sufficiently high that these remain a concern, it is recommended that risk mitigation should be included as the impact is over a much wider area and movement to the wider environment may be possible. For example the storage

of industrially treated timber on impermeable hard standing, to prevent direct losses to soil and allow recovery for re-use or disposal, is proposed as a condition of use.

2.3 Listing 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 IV of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix II.

3 PROPOSAL FOR THE DECISION

3.1 Background to the Proposed Decision

The overall conclusion from the human health evaluation of dichlofluanid, for use in product-type 8 (wood preservatives), is that the active substance in biocidal products containing 0.7% w/w dichlofluanid will not present an unacceptable risk to humans during the proposed normal use. This conclusion relies on the fact that users will be applying the basic principles of good practice and using appropriate and obligatory personnel protective equipment; in particular for the dipping process (including mixing/loading operations) and cleaning out the dipping tank, where considerable contamination of the operator can be anticipated, a higher degree of protection than typical work clothing is warranted. Consequently, it is assumed impermeable coveralls will be worn. Also, to reduce exposure via the hands, operators would be required to wear new protective gloves at the start of each daily dipping session.

For the product considered in this evaluation, it is proposed that dipping is by automated/mechanical means and not carried out manually as originally requested by the applicant. Manual dipping may be acceptable (i.e. MOE of 100 or greater) for other dichlofluanid wood preservative formulations if, for example, they are shown to have a much lower dermal penetration than for the formulation currently under consideration (39.52 % or less).

The results of the secondary exposure risk assessment demonstrate that adults, children and infants will not be exposed to unacceptable levels of dichlofluanid during the realistic worst-case scenarios presented.

The environmental risk assessment indicates that the majority of scenarios investigated for the application and use of timber treated with a wood preservative containing 0.7 % w/w dichlofluanid (with retention of 1.1 g a.s./m^2 or 90 g a.s./m^3), will not result in unacceptable exposure of the aquatic or terrestrial compartments to dichlofluanid or its major metabolite (DMSA). However, mitigation measures are required as a condition of use to remove those concerns that have been identified.

For the aquatic environment: the direct exposure of ponds as a result of *in situ* application, and the in-service leaching from a bridge over a pond have been shown to be of concern as the PEC:PNECs are > 1. Therefore, for *in situ* treatment by brush (professional or amateur), wood preservative products containing dichlofluanid must not be used to treat wooden structures located where direct losses to water cannot be prevented. The use of timber pre-treated with dichlofluanid to construct bridges is not considered to be a concern as such structures are more likely to use impregnated timber and/or timber treated with a different

wood preservative to obtain longer protection. In-service leaching from a noise barrier constructed of treated timber, and all losses predicted for both industrial applications considered did not present an unacceptable risk to surface water.

For the terrestrial environment, the risk to the soil compartment following storage on site (where significant direct exposure of the soil to dichlofluanid is assumed) has to be considered unacceptable because of the scale of contamination predicted over time. Therefore, the timber treated on an industrial site must be stored on hard standing to prevent direct losses to soil. The risk to the soil compartment as a whole following in-service leaching from treated timber (e.g. house, fence) to soil is acceptable despite localised high risk areas, which are considered to be either contained or have been shown not to pose an unacceptable risk to groundwater.

The data on the active substance, dichlofluanid, and the wood preservative product have demonstrated sufficient efficacy against wood-staining fungi (e.g. blue-staining fungi and mould) for inclusion into Annex I to be recommended. However, further efficacy data will be required to support product authorisation at the Member State level.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

3.2 Proposed Decision regarding Inclusion on Annex I

It is recommended that dichlofluanid is included in Annex I of Directive 98/8/EC as an active substance for use in product-type 8 (wood preservatives), subject to the following specific provisions:

1) The active substance dichlofluanid, as manufactured, shall have a minimum purity of 96% w/w.

2) The identity and maximum content of impurities must not differ in such a way as to invalidate the assessment for the inclusion of the active substance on to Annex I.

3) The following particular conditions also apply:

- When industrial/professional operators use products they must wear the appropriate personal protective equipment (see below).

- All timber treated by dipping and automated enclosed spraying must be stored on impermeable hard standing to prevent direct losses to soil and allow losses to be collected for re-use or disposal

- Labels and/or safety data sheets of products authorised for industrial use must indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal

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

1) Products containing dichlofluanid may be used in the pre-treatment of wood by automated/mechanical dipping, including automated enclosed spraying, by

industrial/professional users; and the preservation of wood *in situ* outdoors by brush application, by both professional and amateur (non-professional) users.

2) Member States should be fully aware of their national legislation implementing Article 6 of the Directive 98/24/EC for all substances. For the use of dichlofluanid in this product, the application of personal protection measures includes:

   Industrial /Professional users:

   - for mixing and loading 10 % w/w dichlofluanid concentrate – suitable protective gloves and footwear, cotton coveralls and eye/face protection;

   - for dipping wooden articles (including mixing/loading) – new suitable protective gloves at start of each daily dipping session, protective footwear, impermeable coverall, plus, for mixing/loading, eye/face protection;

   - for handling wet treated timber – suitable protective gloves and cotton coverall;

   - for cleaning out the dipping tank – suitable protective gloves and footwear, impermeable coverall, eye/face protection and RPE.

   Amateur users:

   - for painting (brush application) – suitable cotton coverall, protective gloves and footwear are recommended.

3) Further data on exposure during painting practices are being acquired by AT/DE. Once these data are available, and agreed by the EU, they could be used in product authorisation evaluations for dichlofluanid in wood preservatives.

4) Products must be labelled appropriately to ensure their safe storage, handling, use and disposal in accordance with national arrangements. Member States may wish to consider additional protective measures e.g. child-resistant closures but this was not considered further during the assessment as the product submitted is a representative, rather than an actual, product.

5) When Member States are authorising products, the following must be considered:

- the source and nature of the non-active components within the product (since their classifications could affect the classification of the product).

- the potential for the product to require classification as a sensitiser (as dichlofluanid itself is a sensitiser). It will be important to ensure that mitigation measures (e.g. ventilation and use of gloves) are in place to minimise operator exposure where necessary.

- the efficacy of individual products must be demonstrated.

- The need for a risk assessment for bats.

6) The average adult dietary intake of fluoride within the Member State will need to be considered if this is significantly greater than 0.02 mg fluoride/kg/day (the value used in the human risk characterisation for fluorosis during this evaluation).

7) Because of the potential risk to the aquativc environment during each member states product authorisation process the following should be considered:

   - No in situ application by brush to wooden structures near water should be permitted, unless direct losses to the aquatic compartment can be prevented.
   - Whether hazard class 3 timbers are used for structures near to water.
   - The potential for contamination of groundwater.

8) The need to address any specific national conditions and/or undertake regional assessments should be considered, as only local environmental risk assessments have been carried out in this evaluation.

9) Timber, whether treated *in situ* or pre-treated, (with a retention of up to 1.1 g a.s./m^2 or 90 g a.s./m^3 wood) must not be in contact with surface water or the ground (i.e. up to and including Hazard Class 3).

10) Manual dipping may not be permitted for the representative product considered in this evaluation. However it may be possible to allow manual dipping for other (real) products, containing dichlofluanid provided data are submitted to show that occupational exposure is acceptable.

11) Losses during industrial/professional application by the dipping and automated enclosed spraying processes, as well as during tank cleaning, must be contained and recycled; or collected and treated as waste in accordance with the national regulations of the Member State authorising individual products.

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 dichlofluanid on to Annex I of the Directive 98/8/EC.

Manual dipping may be acceptable (i.e. MOE of 100 or greater) for other dichlofluanid wood preservative formulations if, for example, they are shown to have a much lower dermal penetration than for the formulation currently under consideration (39.52% or less).

The conditions and restrictions proposed are considered reasonable, and no further information is required. However, the future provision of additional terrestrial toxicity data may allow the removal of the risk mitigation measures (hard standing) for the on-site storage of treated timber.

3.5 Updating this Evaluation Report

The technical information in this evaluation 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 the framework of 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 inclusion conditions for dichlofluanid on to Annex I of the Directive.

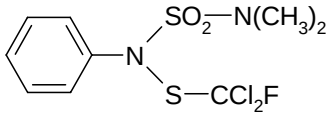
APPENDIX I

Identity, Physical and Chemical Properties

DICHLOFLUANID

Identity

Chemical name (IUPAC)	N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-phenylsulfamide
Chemical name (CA)	Methanesulfenamide, 1,1-dichloro-N-[(dimethylamino)sulfonyl]-1-fluoro-N-phenyl-
CAS No	1085-98-9
EC No	214-118-7
Other substance No.	CIPAC No 74
Minimum purity of the active substance as manufactured	≥ 960 g/kg ≥ 96 % w/w
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured	The identity and concentrations of the impurities in dichlofluanid, and the additives are confidential. This information is provided in the 'Confidential Annex' document which is part of the CA report
Molecular formula	$C_9H_{11}Cl_2FN_2O_2S_2$

Molecular mass	333.2
Structural formula	

Physical and chemical properties

Active substance

Melting point	103.2 °C at the beginning of melting, 104 °C at final stage of melting (purity: 99.4%)
Boiling point	Not measurable, substance decomposes and is not distillable
Temperature of decomposition	DTA: endothermic effect (melting) < 150 °C, no exothermic effect (decomposition); TGA: weight loss due to evaporation, sublimation and transition to decomposition, commencing at 120 °C. Dichlofluanid may be considered stable at room temperature
Appearance	At 20 °C and 101.3 kPa: Physical state: solid powder Colour: white to slightly yellow Odour: characteristic smell, musty
Relative density	1.575 at 20 °C (purity: 96%)
Surface tension	72.75 mN/m; not surface active (test solution concentration was 1.17 mg/l)
Vapour pressure	2.15×10^{-5} Pa at 20 °C 5.37×10^{-5} Pa at 25 °C 3.03×10^{-3} Pa at 50 °C
Henry's law constant	4.5×10^{-3} Pa .m^3.mol^{-1}
Solubility in water	pH 4: 0.92 mg/l at 10 °C 1.58 mg/l at 20 °C 2.69 mg/l at 30 °C The solubility in water is independent of pH in the range of pH 4 to pH 9. However it hydrolyses in water especially at higher pHs.
Solubility in organic solvents	Results at 20 °C: Xylene: 81.2 g/l Shellsol D60: 2.54 g/l Di(propylene glycol)methyl ether: 86.4 g/l 2-Methyl-2,4-pentanediol: 20.7 g/l Due to the decomposition of dichlofluanid in 1-methyl-2-pyrrolidone, the solubility in this solvent cannot be determined
Stability in organic solvents used in biocidal products including relevant breakdown	Dichlofluanid, in a representative solvent-based

products	wood preservative, is stable for 8 weeks at 40°C.
Partition coefficient (log P_{OW})	log P_{ow} = 3.5 The partition coefficient was determined to be independent of temperature in the range of 10 °C to 30 °C and to be independent of pH in the range pH 4 to pH 9
Dissociation constant	Dichlofluanid has no acidic or basic properties in water in the range pH 4 to pH 9
UV/VIS absorption (max.)	Spectra confirms the chemical structure
Flammability	Dichlofluanid (tested as Preventol A 4-S) is not highly flammable according to EC Test Method A.10. It does not liberate gases in hazardous amounts upon contact with water. It shows spontaneous combustion behaviour. The relative spontaneous ignition temperature is 370 °C
Explosive properties	From the chemical structure of dichlofluanid it can be concluded that dichlofluanid is not explosive
Oxidizing properties	From the chemical structure it is seen that dichlofluanid will not react exothermally with flammable materials. Therefore dichlofluanid does not exhibit any oxidizing properties
Reactivity towards container material	Based on information from experience of packaging dichlofluanid and its chemical structure, the recommended container materials for direct contact with dichlofluanid are: Polypropylene plastic material (PP), High and low density Polyethylene plastic materials (HDPE, LDPE)

Metabolite, DMSA

Vapour pressure	2.5×10^{-4} Pa at 20 °C; 4.9×10^{-4} Pa at 25 °C
Henry's Law Constant	3.8×10^{-5} $Pa.m^3.mol^{-1}$
Solubility in water	1.3 g/l at 20 °C
Dissociation constant	At 20 °C: 2.0×10^{-9}; pK(a) value: 8.7
Partition coefficient n-octanol/water	At 20 °C: P_{ow} = 39; log P_{ow} = 1.59

APPENDIX II

End Points and Related Information

DICHLOFLUANID

Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rat: ^{14}C ring labelled dichlofluanid: ≥ 90 % absorption, with maximum concentration in blood plasma within 3.0 hours Rat: ^{14}C labelled fluorodichloromethyl sulphenyl group: 70 – 80 % absorption with maximum relative concentration in blood plasma within 1.5 hours
Rate and extent of dermal absorption:	A typical wood preservation formulation of dichlofluanid in a mineral oil preparation at a concentration of about 0.55 % w/w was used in this study. [^{14}C]-dichlofluanid was applied in a test preparation to human split-thickness skin membranes mounted in flow-through diffusion cells *in vitro*. Receptor fluid, ethanol:water (1:1, v/v) was collected in hourly fractions from 0 – 6 hour post-dose and then in 2 hourly fractions from 6 – 24 hours post-dose. The skin was washed with soap and dried with tissue swabs. Of the applied dose, 37.37 % of the active substance was found to cross the skin into the receptor fluid, with a further 22.48% retained within the stratum corneum and 8.09 % below the stratum corneum. The UK CA has concluded that a reasonable approach is to assume that all the dichlofluanid that has moved below the stratum corneum (37.37 + 8.09) is absorbed. This therefore gives a dermal absorption value of 45.46 %.
Rate and extent of inhalational absorption	
Distribution:	Widely distributed with generally low concentrations, except for liver, kidney, thyroid and erythrocytes.
Potential for accumulation:	No. Dichlofluanid was found to not accumulate in the carcass or carcass minus gastrointestinal tract.
Rate and extent of excretion:	≥ 99% during the first 48 hours after oral

	application; mainly via urine, but also via faeces and the breath.
Toxicologically significant metabolite	Parent compound, fluoride ion

Acute toxicity

Rat LD_{50} oral	> 5000 mg/kg (males + females)
Rat LD_{50} dermal	> 2000 mg/kg (males + females)
Rat LC_{50} inhalation Mouse LC_{50} inhalation	About 1200 mg/m^3/4 h (males + females)
Skin irritation	Not classified for this effect.
Eye irritation	Irritating to eyes
Skin sensitization	Sensitising (Magnusson-Kligman test)

Repeated dose toxicity

Species/ target/critical effect	Dogs – liver (disturbance of liver function and hepatic cell damage), kidney (nephropathy and disturbance of kidney function), thyroid (reduction of thyroid hormones) Rats – thyroid (reduction of thyroid hormones)
Lowest relevant oral NOAEL/LOAEL	$NOAEL_{short\text{-}term}$ of 20-24 mg/kg/day (subchronic dog) $NOAEL_{long\text{-}term}$ of 2.5 mg/kg/day (chronic dog)

Species/ target/critical effect	Rats – bone (osteosclerosis)
Lowest relevant NOAEL/LOAEL	LOAEL of 9.4-13.5 mg/kg/day
Lowest relevant dermal NOAEL/LOAEL	NOAEL for systemic effects of ≥ 1000 mg/kg/day (subacute rat)
Lowest relevant inhalation NOAEL/LOAEL	Not available

Genotoxicity	Dichlofluanid was found to be a point mutagen in studies on bacteria and in the mouse lymphoma strain L5178Y at cytotoxic concentrations. Further *in vitro* tests on point mutations on the HPRT locus in eukaryotic cells yielded negative results. The available data indicate that dichlofluanid was not an *in vivo* somatic or germ cell mutagen.

Carcinogenicity

Species/type of tumour	No primary carcinogenic effect

Reproductive toxicity

Species/reproduction target/critical effect	Rat: Pups – reduced weights, elevated liver and kidney weights
Lowest relevant NOAEL	NOAEL (parental) of 180 ppm equiv. to 16/21 mg/kg/day (m/f)
Species/developmental target / critical effect	No compound related effects on development
Lowest relevant NOAEL	NOAEL of 30 mg/kg/day

Neurotoxicity

Species/target/critical effect	No indications for special concern

Medical data

No indications for special concern. A few cases of allergic skin reactions are described among manufacturing plant personnel.

Summary	Value	Study	Safety factor
ADI (if residues in food or feed)	0.35 mg/kg/day	Human studies for fluorosis	Not relevant
$AOEL_{short-term}$	0.2 mg/kg/day	Subchronic, oral dog	100
$AOEL_{long-term}$	0.025mg/kg/day	Chronic, oral dog	100
Drinking water limit	0.1 µg/l	As set by EU Drinking Water Directive (98/83/EC)	Not relevant.
ARfD (acute reference dose)	Not required for dichlofluanid in wood preservatives	Not relevant.	Not relevant.

Acceptable exposure scenarios (including method of calculation)

Industrial/professional mixing, loading and dipping (including automated enclosed spraying)

Mixing & loading:
Concentrate contains 10 % w/w a.s. to be diluted to a 0.7 % w/w a.s. in-use dipping fluid
One event per day of 10 minutes duration

Total systemic exposure: 0.0288 mg/kg/day

PPE: suitable cotton coverall, protective gloves and footwear, eye/face protection *Application:* Concentrate contains 10 % w/w a.s. to be diluted to a 0.7 % w/w a.s. in-use dipping fluid One event per day, 30 minutes per event PPE: new suitable protective gloves at start of each daily dipping session, protective footwear, and impermeable coveralls plus for mixing and loading, eye/face protection	
Industrial/professional cleaning of the dipping tank (without RPE) Dipping tank containing 0.7 % w/w a.s. dipping fluid Cleaning undertaken infrequently (possibly once a year) for up to 180 minutes during the day PPE: suitable protective gloves and footwear, impermeable coveralls and eye/face protection	Total systemic exposure: 0.0115 mg/kg/day
Professional application by brush In-use product contains 0.7 % w/w a.s. One event/day of 150 minutes duration PPE: suitable protective gloves, footwear and cotton coverall	Total systemic exposure: 0.0131 mg/kg/day
Industrial/professional users handling treated wet timber Following treatment of timber with 0.7 % w/w a.s. dipping fluid Intermittent handling for up to 180 minutes/day PPE: suitable protective gloves, footwear and cotton coverall	Total systemic exposure: 0.0117 mg/kg/day

Amateur application by brush (no gloves) **In-use product contains 0.7 % w/w a.s.** One event/day of 150 minutes duration PPE: none	Total systemic exposure: 0.0919 mg/kg/day

Secondary exposure

Acute phase	MOE: Adult (amateur sanding treated wood): 14,286 Child: not relevant Infant: 847
Chronic phase	MOE: Adult (cleaning work clothes at home): 159 Adult/Child/Infant (inhaling volatilised residues indoors): not relevant Adult (professional sanding): 1,563 Child: 926 Infant (modified): 195

Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolytic stability (active substance) (DT_{50})	pH 9: At pH 9, the hydrolytic degradation was so rapid that at room temperature, even when the analysis was conducted immediately, no dichlofluanid could be detected. pH 7: DT_{50} (20°C) = 25.6 h, DT_{50} (30°C) = 5.4 h, DT_{50} (22°C, extrapolated) = 18.8 h. pH 4: DT_{50} (30°C) = 6.9 d, DT_{50} (40°C) = 2.8 d, DT_{50} (22°C, extrapolated) = 15.3 d.
Hydrolytic stability (relevant metabolites) (DT_{50})	No hydrolysis of DMSA was detectable DT_{50} > 1 year at pH 4, 7 and 9 at 22 °C.
Photostability (DT_{50})	Due to its lack of UV absorbance at the wavelengths present in sunlight, dichlofluanid is not degradable by direct photodegradation in aqueous solution. Even under the assumption of a quantum yield of 1, assessments of the environmental half-life by means of computer models would yield values of several years
Quantum yield of direct phototransformation in water at Σ > 290 nm	See above
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Dichlofluanid does not absorb any light at wavelengths above 287 nm. Therefore, it is not degradable by direct photodegradation.
Ready biodegradation (active substance)	Classification: Not readily biodegradable.

	Results: 9 % after 28 days, and 41 % after 140 days.
Ready biodegradation (metabolite)	Classification: Not readily biodegradable. Degradation did occur with pre-adapted sludge. Results: 63% after 28 days in adapted sewage sludge.
Degradation in seawater (hydrolysis of active substance)	pH 8.2: DT_{50} (10°C) = 3.27 h, DT_{50} (20°C) = 1.21 h, DT_{50} (25°C) = 0.77 h.
Non-extractable residues	Non-extractable residues were found in water-sediment studies (about 18 % after 120 days).
Distribution in water / sediment systems (active substance)	Dichlofluanid was rapidly degraded in two aerobic aquatic systems with DT_{50} values of 1.2 and 3 h. Dichlofluanid does not constitute a lasting potential to contaminate surface water or sediment.
Distribution in water / sediment systems (metabolites)	Dichlofluanid was very rapidly degraded in aerobic aquatic systems to DMSA. DMSA stayed mainly in the water phase. No further metabolite approaching or exceeding the 10 % mark within the incubation time.

Route and rate of degradation in soil

Mineralization (aerobic)	Up to 22.6 % after 414 d.
Laboratory studies	DT_{50lab} (20°C, aerobic): < 1 day. Dichlofluanid is rapidly degraded in biologically active soils (sandy loam and sand soils) to DMSA. No half-life is available for DMSA, although maximum levels of DMSA were reported around day 8 (~ 90 % AR) in biologically active soils, indicating the half-life was likely to be between 58 and 97 d, depending on soil type.
Field studies	Not available
Anaerobic degradation	DT_{50lab} (20 °C, anaerobic): < 30 d (First sampled on day 30, when 87.4-95.5 % of the dichlofluanid was degraded to DMSA). Under anaerobic conditions in soil dichlofluanid is rapidly degraded to DMSA.
Soil photolysis	No data available
Non-extractable residues	Aerobic: Under aerobic conditions the bound residues reported were 56 % after 181 d, 69.4 % after 183 d and 75.7 % after 414 d. Anaerobic: Under anaerobic conditions the bound residues reached a maximum of 20.5 % after 61 d after which they declined.

Relevant metabolites - name and/or code, % of applied a.i.	Formation of DMSA from dichlofluanid: Aerobic: 79.5-84.0 % after 1 d Anaerobic: 87.4-95.5 % 30 d.
Leaching in soil	Dichlofluanid was not detected in any of the leachate analysed, and the major proportion of AR was as DMSA, in amounts ranging from 10 % - 30 % depending on the formulation and application technique. In aged soil 65.5% of the recovered radioactivity was associated with the leachate, of which < 1% was dichlofluanid and the majority was DMSA (62 % after 30 days). After 90 days the level of radioactivity recovered in the leachate was only 3% none of which was DMSA.

Adsorption/desorption

Ka, Kd Ka_{oc}, Kd_{oc} pH dependence	Dichlofluanid; K_{oc} = 1344 (log K_{oc} = 3.13) DMSA; K_{oc} = 53 (log K_{oc} = 1.72)

Fate and behaviour in air

Direct photolysis in air	Concerning the overall relevance of the atmospheric fate of dichlofluanid the very low vapour pressure of the compound has to be taken into account. Air will not be an environmental compartment of concern for dichlofluanid used in wood preservatives.
Photo-oxidative degradation in air	DT_{50}: QSAR study (non-key) gave a half–life in air of 8.6 h – corresponding to a chemical life-time in air of about 12.5 h.
Volatilization	Insignificant due to low vapour pressure and low Henry constant.

Monitoring data, if available

Soil	Not available
Surface water	Not available
Ground water	Not available
Air	Not available

Effects on Non-target Species

Toxicity data for aquatic species

Species	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Fish				
Salmo gairdneri	**Dichlofluanid**	96 hours	Mortality	LC_{50} = 0.01 mg/l
Salmo gairdneri	Dichlofluanid	21 days	Mortality and symptoms	NOEC = 0.00455 mg/l
Pimephales promelas	Dichlofluanid	33 days	Body length & weight	NOEC = 0.00407 mg/l
Salmo gairdneri (Oncorhynchus mykiss)	DMSA	21 days	Mortality Body weight and length	LC_{50} > 100 mg/l NOEC = 10 mg/l
Invertebrates				
Daphnia magna	Dichlofluanid	48 hours	Immobility	EC_{50} = 0.42 mg/l
Daphnia magna	Dichlofluanid	21 days	Reproduction, Body length & weight	NOEC = 0.00265 mg/l
Daphnia magna	DMSA	48 hours	Immobility	$EC_0 \geq$ 95.6 mg/l
Chironomus riparius	DMSA	28 days	Development	EC_5 = 9.7 mg/l
Algae				
Scenedesmus subspicatus	Dichlofluanid	72 hours 96 hours	Growth Rate Growth Rate	E_rC_{50} = 15.0 mg/l NOE_rC = 1 mg/l
Scenedesmus subspicatus	DMSA	72 hours	Growth Rate	NOEC $\geq$ 97.7 mg/l
Microorganisms				
Activated sludge	Dichlofluanid	3 hours	Inhibition of respiratory rate	EC_{50} = 19 mg/l
Activated sludge	DMSA	30 mins	Inhibition of respiratory rate	EC_{50} = 1140 mg/l

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	*Eisenia fetida andrei*: LC_{50} (14 days) > 913 mg/kg dwt soil

Effects on soil micro-organisms

Nitrogen mineralization Carbon mineralization	Dichlofluanid will not cause adverse effects to the soil carbon and nitrogen cycle at the concentration of 3.41 mg a.s./kg dwt soil. A dose of 34.1 mg a.s./kg dwt soil caused a reduction in the amount of glucose degraded. This dose also induced a temporary inhibition and, subsequently, a temporary stimulation of nitrogen mineralisation in both soils.

Effects on terrestrial vertebrates

Acute toxicity to birds	*Colinus virginianus*: LD_{50} > 2226 mg/kg bw
Sub-acute toxicity to birds	*Colinus virginianus, Anas platyrhynchos*: subacute toxicity (5 days) LC_{50} > 5000 mg/kg feed

Effects on terrestrial plants

Acute toxicity	*Brassica napus, Glycine max, Avena sativa:* EC_{50} > 100 mg/kg soil

Effects on other beneficial arthropods

Acute toxicity	Not available

Bioconcentration

Bioconcentration factor (BCF)	*Lepomis macrochirus* : edible: 61 (±09), whole fish: 72 (±14).
Depuration time (DT_{50}) (DT_{90})	DT_{50} (days) : edible: 0.25 (±0.03), whole fish: 0.24 (±0.03).
Level of metabolites (%) in organisms accounting for > 10 % of residues	No metabolites identified

APPENDIX III

List of Uses Supported by Available Data

DICHLOFLUANID

Dichlofluanid is effective against wood-staining fungi (blue-stain and mould).

The product considered was a representative product rather than a real one and was considered to be supplied as a ready for use (RFU) solvent based product or as a concentrate (containing 10% dichlofluanid) diluted down to the RFU concentration. The concentrate is only available for industrial & professional users.

Product type	**Field of use envisaged** **----------** **Solvent based product**	**Likely concentration at which the active substance will be used in % weight/weight**	**Effective retention in wood in gram a.s./m² or a.s./m³**
8	Dipping /Automated Enclosed Spraying of Wooden Articles (industrial/professional users)	0.55 - 0.7	1.1 g/m² / 90 g/m³
8	Painting by brushing (professional users)	0.55 - 0.7	1.1 g/m²
8	Painting by brushing (amateur users)	0.55 - 0.7	1.1 g/m²

APPENDIX IV

List of Studies

DICHLOFLUANID

The References/Studies listed below are those included in the UK CA report for Dichlofluanid in wood preservatives (PT8).

Data protection is claimed by Lanxess Deutschland GmbH in accordance with Article 12.1 (c) of Council Directive 98/8/EC for all studies marked Yes in the Data Protection Claimed (Yes/No) column.

For studies marked Yes (1) the data have been seen before by the UK CA (HSE), as part of a national review on dichlofluanid in antifoulants in 2000, and have been data protected from 21st November 2001 for 5 years. Hence data protection on these studies will expire on 21st November 2006, so these studies can then receive data protection until 13/05/2010 in all Member States other than the UK, according to Article 12.1 (c) (i) of Directive 98/8/EC. The study number related to its previous submission to the UK is noted in square brackets.

For studies marked Yes (2) the data have not been reviewed previously by the UK CA (HSE), and hence data protection should be granted for 10 years from the date when the active substance is first listed on Annex I according to Article 12.1 (c) (ii) of Directive 98/8/EC. It is assumed that the relevant studies are not already protected in any other MS of the European Union under existing national rules relating to biocidal products.

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
Anderson, J.P.E.	1991a	Influence of the Commercial Product Euparen WG 50 on the Soil Respiration after Amendment with Glucose.	Bayer AG	AJO/91490	Yes	No	Yes (2)	Bayer CropScience AG	A7.5.1.1
Anderson, J.P.E.	1991b	Influence of the Commercial Product Euparen WG 50 on the Microbial Mineralization of Carbon in Soils.	Bayer AG	AJO/91690	Yes	No	Yes (2)	Bayer CropScience AG	A7.5.1.1
Anderson, J.P.E.	1991c	Influence of the commercial product Euparen WG 50 on Nitrogen Mineralization in Soil.	Bayer AG	AJO/91590	Yes	No	Yes (2)	Bayer CropScience AG	A7.5.1.1
BAM (Gersonde & Kerner)	1974	Application to Test Primers for Resistance to Blue-Stain	Bundesanstalt für Materialprüfung (BAM), Berlin	Test Certificate Ref. 5.1/1974, 1st Issue	No	No	Yes (2)	Bayer AG	Non-key study
Barrueco, C. & de la Pena, E.	1988	Mutagenic evaluation of the pesticides captan, folpet, captafol, Dichlofluanid and related compounds with the mutants TA102 and TA104 of Salmonella typhimurium. *Mutagenesis*. 1988 Nov; 3(6): 467-80.	_	_	_	Yes	No	_	Published
Bayer AG	2004	Determination of surface tension using the du Nouy interfacial tensiometer.	Bayer Technology Services, Germany	A0306898/0 (2003/12213)	No	No	Yes (2)	Bayer Chemicals AG	B3 (3.10)
Bayer AG	2002	Preventol A 4-S - Chemical Composition.	Bayer AG	_	No	No	Yes (2)	Bayer Chemicals AG	Confidential Annex only
Bayer Chemicals	2003	*Safety Data Sheet "Preventol A 4-S"*	Bayer AG	014730/ 28	_	Yes	No	Bayer Chemicals	A3 (3.1, 3.3) A8

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
Bayer Chemicals	2004	"JJT 3581 - Dichlofluanid solvent-based guide recipe" Material Safety Data Sheet.	_	MSDS No. 288067/00	No	No	No	Bayer Chemicals	B3 (3.1) B8
Bayer Material Science AG	2004	Alkydal F 681 TBA Material Safety Data Sheet	_	023918/09	No	Yes	No	Bayer Material Science	Published
Benford, D.J.	1988	Ex vivo *hepatocyte UDS study with KUE 13032 C.*	The Robens Institute, University of Surrey, UK; Bayer AG	R 4593	Yes	No	Yes (1) [BR 051/049]	Bayer CropScience AG	A6.6.4
Berthold, K.	2004	Letter Re: Christenson, Elcock; Technical grade Dichlofluanid (Euparen VM 90): Oral dosing chronic toxicity studies in the beagle dog; Report No: R 5832 – Determination of NOEL/NOAEL.	Bayer HealthCare AG	LETTER	No	No	Yes (2)	Bayer Chemicals AG	A6.5
Bomhard, E.; Loeser, E.	1980a	*Preventol A 4 - Study on Guinea pigs for sensitizing effect ("Draize Test").*	Bayer AG	8898	No	No	Yes (1) [BR 051/026]	Bayer Chemicals AG	Non-key study
Bomhard, E.; Loeser, E.	1980b	*Preventol A 4 - Study for sensitizing effect in the open epicutaneous test.*	Bayer AG	9512	No	No	Yes (1) [BR 051/025]	Bayer Chemicals AG	Non-key study
Bomhard, E.; Loeser, E.; Schilde, B.	1980	Preventol A 4 - Study for sensitising effect (Magnusson and Kligman's maximisation test).	Bayer AG	8951	No	No	Yes (1) [BR 051/026]	Bayer Chemicals AG	A6.1.5
Bond, G.P.	1986	Acute dermal toxicity of Preventol A 4-S in Albino Rabbits.	Mobay Corp., USA Bayer AG	744	Yes	No	Yes (1) [BR 051/038]	Bayer Chemicals AG	A6.1.2
Bornatsch, W.;	1986	*Structural clarification of*	Bayer AG	PF 2710	No	No	Yes (1)	Bayer	A6.2

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
Brauner, A.		*metabolites of [ring-U-^{14}C]dichlofluanid in rat feces.*		(MR 94280)			[BR 051/042]	CropScience AG	
Bravery, A.F.; Dickinson, D.J.	1984	Artificial weathering as an aid to assessing the effectiveness of chemicals for preventing blue stain in service - a co-operative study. Published for 15th annual meeting in Sweden (1984-05-28-1984-06-01)	The International Research Group On Wood Preservation, Working Group Ii (Fundamentals Of Testing), Subgroup 4	Document No. IRG/WP/2215	No	Yes	No	-	Published
Briggs, G.G.	1973	A simple relationship between soil adsorption of organic chemicals and their octanol/water partition coefficients. Proc. 7th British Insecticide and Fungicide Conference, Nottingham, UK 83-86	_	_	_	Yes	No	_	Published
Building Research Establishment	Ed. 1992	Effectiveness of Preventol A4-S as a Wood Preservative against Blue Stain.	BRE Technical Consultancy	Client Report No: TCR50	No	No	Yes (2)	Bayer AG	Non-key study
Caspers, N.	1997a	DMSA - Acute Daphnia Toxicity.	Bayer AG	689A/97D	Yes	No	Yes (2)	Bayer CropScience AG	A7.4.1.2
Caspers, N.	1997b	DMSA - Alga Growth Inhibition Test.	Bayer AG	689A/97Al	Yes	No	Yes (2)	Bayer AG	A7.4.1.3
Christenson, W.R.; Elcock, E.L.	1992	Technical grade Dichlofluanid (Euparen VM 90): Oral dosing chronic toxicity studies on the Beagle dog.	Miles Inc, USA	R 5832	Yes	No	Yes (1) [BR 051/056]	Bayer CropScience AG	A6.5
Cifone, M.A.	1985	Mutagenicity evaluation of KUE	Litton Bionetics,	R 3327	Yes	No	Yes (1)	Bayer	A6.6.3

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
		13032 C (VM) - c n. Dichlofluanid - in the mouse lymphoma forward mutations assay.	USA; Bayer AG	(E9301)			[BR 051/036]	CropScience AG	
COT	2003	UK Committee on Toxicity of chemicals in food, consumer products and the environment. Statement on Fluorine in the 1997 Total Diet Study. Available at: http://www food.gov.uk/science/ouradvisors/toxicity/statements/cotstatements2003/fluorine	_	_	No	Yes	No	_	-
Dow Chemicals	2003	Dowanol DPM Material Safety Data Sheet	_	_	No	Yes	No	Dow Chemicals	Published
Eben, A.; Kimmerle, G.	1968	*Studies on the metabolism of BAY 47531.*	Bayer AG	856	No	No	Yes (2)	Bayer CropScience AG	Non-key study
EC (European Commission)	2003	Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Commission Directive 98/8/EEC concerning the Placing of Biocidal Products on the market.	_	_	_	Yes	No	European Chemical Bureau (ECB), Joint Research Centre JRC), Ispra, Italy	Published
EC	2002a	Technical Notes of Guidance (TNsG) in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market Human Exposure to Biocidal	_	Document CA-Jul 02-Doc.7.2, Final June 2002.	No	Yes	No	European Chemical Bureau (ECB), Joint Research Centre JRC), Ispra, Italy	Published

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
		Products. Along with User Guidance.		User Guidance version 1 (Jun 2002)					
EC	2002b	Technical Notes of Guidance (TNsG) in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market – TNsG on Annex I inclusion.	_	_	No	Yes	No	European Chemical Bureau (ECB), Joint Research Centre JRC), Ispra, Italy	Published
ECB (European Chemicals Bureau)	2005	Leaching Workshop. Summary published in ECB newsletter dated 28th July 2005	_	_	No	Yes	No	European Chemical Bureau JRC, Ispra, Italy	Published
ECB	1999	Summary Record of Conclusions of the Commission Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity, Meeting 1-2 September 1999.	_	ECBI/49/99	_	Yes	No	ECB, Ispra, Italy	Published
ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)	2001	Exposure Factors Source book for European Populations (with focus On UK data)	_	Technical Report No. 79	No	Yes	No	ECETOC	Published
Ecker, W.	1978	Biotransformation of [^{14}C] Dichlofluanid in the Rat.	Bayer AG	Pharma Report 7177 (PF 1265)	No	No	Yes (1) [BR 051/020]	Bayer CropScience AG	A6.2
Eigenberg, D.A.; Lake S.G.	2004	Technical Grade Dichlofluanid (Euparen) - A 90-Day Subchronic Toxicity Feeding Study in the Beagle Dog.	Bayer Cropscience LP, USA	200831	Yes	No	Yes (2)	Bayer Cropscience AG	A6.4.1
Elcock, E.L.	1996	Addendum to the original Bayer report No. R 5832: Technical grade	Miles Inc, USA	7934	*Yes*	No	Yes (2)	Bayer CropScience AG	A6.5

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
		Dichlofluanid (Euparen VM 90): Oral dosing chronic toxicity studies on the Beagle dog (from Christenson & Elcock)							
Erstling, K.	2001	Abiotic Degradation.	Bayer AG	G 01/0142/01 LEV	Yes	No	Yes (2)	Bayer Chemicals AG	A7.1.1.1.1
Faul, J.	1989	Euparen and Euparen M - In-Company Occupational Medical Experience.	Bayer AG	LETTER	No	No	Yes (2)	Bayer CropScience AG	A6.12
Faul, J.	1982	Statement to Pkt IV/1.2.2 of the BBA application form "Details of effects on man, internal company experience".	Bayer AG	LETTER	No	No	Yes (1) [BR 051/032]	Bayer CropScience AG	A6.12
Fennert, E.-M.	2004	Test Report for JJT 3581. Laboratory Study for determining the protective effectiveness against blue strain according to EN 152 part 1 (08/98).	Materialprüfung samt des Landes Brandenburg, Germany; Bayer AG	3.2/04/8540/ 01	No	No	Yes (2)	Bayer Chemicals AG	B5.10
Forbis, A.D.	1986	*Acute flow-through toxicity of Preventol A 4-S to Daphnia magna.*	ABC Laboratories Inc., USA; Bayer AG	778	Yes	No	Yes (2)	Bayer Chemicals AG	A7.4.1.2
Flucke, W.	1978	*Euparen 90 VM (KUE 13032 C) - Acute toxicity studies in rats, mice, guinea pigs, rabbits and cats.*	Bayer AG	8004	No	No	Yes (1) [BR 051/021]	Bayer CropScience AG	Non-key study
FRAC (Fungicide Resistance Action Committee)	2003	Fungicide Resistance Action Committee List (2003-06-02)	–	–	No	Yes	No	FRAC	Published
Grau, R.	1989	Toxicity of Dichlofluanide techn. (VM 90) for Rainbow Trout (*Salmo*	Bayer AG	FF - 246	Yes	No	Yes (2)	Bayer CropScience AG	A7.4.3.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
		gairdneri) with prolonged exposure (21 days).							
Grau, R.	1990	Toxicity of DMSA for Rainbow Trout (*Oncorhynchus Mykiss*) with prolonged exposure (21 days).	Bayer AG	FF - 290	Yes	No	Yes (2)	Bayer CropScience AG	A7.4.3.1
Grau, R.	1991	*Dichlofluanid - Bioconcentration in Fish.*	Bayer AG	BF-006	Yes	No	Yes (1) [BR 051/073]	Bayer CropScience AG	A7.4.2
Grau, R.	2004	Classification of Dichlofluanid with R53.	Bayer Cropscience AG	_	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Hamburger	1987	*Preventol A4, Toxicity to Bacteria.*	Bayer AG	87142881	No	No	Yes (1) [BR 051/081]	Bayer Chemicals AG	Non-key study
Heil J., G. Reifferscheid, D. Hellmich, M. Hergenroder & Zahn, R.K.	1991	Genotoxicity of the fungicide Dichlofluanid in seven assays. *Environ Mol Mutagen.* 1991; 17(1): 20-6.	_	_	_	Yes	No	_	Published
Heimbach, F.	1983	*Acute Toxicity of Dichlofluanid (90 % premix) to Water Fleas.*	Bayer AG	,Hb/Dm 21	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Heimbach, F.	1985	*Growth inhibition of Green Algae (Scenedesmus subspicatus) by Dichlofluanid (90 % Premix).*	Bayer AG	HBF/Al 13	No	No	Yes (1) [BR 051/074]	Bayer CropScience AG	Non-key study
Heimbach, F.	1989	Toxicity of Euparen (WG) to Earthworms.	Bayer AG	HBF/RG 101	Yes	No	Yes (2)	Bayer CropScience AG	A7.5.1.2
Heimbach, F.	1999	Influence of Dimethylaminosulfanilid (DMSA) on Development and Emergence of Larvae of *Chironomus riparius* in a Water-Sediment System.	Bayer AG	HBF/Ch 31	Yes	No	Yes (2)	Bayer CropScience AG	A7.4.3.5.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
Heinz, U.	2003	Determination of safety-relevant data of Preventol A 4-S.	Bayer Industry Services	03/00256	Yes	No	Yes (2)	Bayer Chemicals AG	A3 (3.11, 312, 3.15 & 3.16)
Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JJT 3581.	Bayer Industry Services GmbH; Bayer AG	2003/12213	No	No	Yes (2)	Bayer Chemicals AG	B3 (3.4-3.6, 3.10, 3.11)
Hellpointner, E.	1990	*Assessment of the environmental half-life of the direct photodegradation of Dichlofluanid in water.*	Bayer AG	PF-3449	Yes	No	Yes (2)	Bayer CropScience AG	A7.1.1.1.2
Hellpointner, E.	1997	*Calculation of the chemical lifetime of Dichlofluanid in the troposphere.*	Bayer AG	PF-4305	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Herbold, B.	1978	KUE 13032 C - Micronucleus test for mutagenic effects on mice.	Bayer AG	8027	No	No	Yes (1) [BR 051/022]	Bayer CropScience AG	A6.6.4
Herbold, B.	1979a	*KUE 13032 C - Salmonella/microsome test for the investigation of point-mutagenic effects.*	Bayer AG	8204	No	No	Yes (1) [BR 051/023]	Bayer CropScience AG	Non-key study
Herbold, B.	1979b	*Preventol A 4 - Salmonella/microsome test for the investigation of point-mutagenic effects.*	Bayer AG	8585	No	No	Yes (2)	Bayer Chemicals AG	Non-key study
Herbold, B.	1979c	*KUE 13032 C - Cytogenetic studies of spermatogoniae of Chinese hamsters to test for mutagenic effects.*	Bayer AG	8432	No	No	Yes (1) [BR 051/024]	Bayer CropScience AG	Non-key study
Herbold, B.	1980a	*Salmonella / Microsome Test To Investigate Point-Mutagenic Action.*	Bayer AG	8849	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Herbold, B.	1980b	KUE 13032 C - Sister chromatid	Bayer AG	9391	No	No	Yes (1)	Bayer	Non-key study

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		exchange on the Chinese hamster in vivo to evaluate for mutagenic effect.					[BR 051/027]	CropScience AG	
Herbold, B.	1984	*KUE 13032 C - Dichlofluanid - Salmonella/microsome test to evaluate for potential point mutation.*	Bayer AG	12834	No	No	Yes (1) [BR 051/035]	Bayer CropScience AG	A6.6.1
Herbold, B.	1986a	*KUE 13032 C - c.n. Dichlofluanid -* In vitro *cytogenetic study on human lymphocyte cultures to evaluate for chromosome-damaging effects.*	Bayer AG	14707	Yes	No	Yes (1) [BR 051/039]	Bayer CropScience AG	A6.6.2
Herbold, B.	1986b	*KUE 13032 C - Dichlofluanid - Dominant lethal test on the male mouse to assess for mutagenic effects.*	Bayer AG	15150	Yes	No	Yes (1) [BR 051/041]	Bayer CropScience AG	A6.6.6
Herbold, B.	1988a	KUE 13032 C - c.n. Dichlofluanid - *In vivo* study of the bone marrow in Chinese hamsters to evaluate for a chromosome-damaging effect.	Bayer AG	16509	Yes	No	Yes (1) [BR 051/044]	Bayer CropScience AG	A6.6.4
Herbold, B.	1988b	*KUE 13032 C - c.n. Dichlofluanid - Spot Test on cross-bred C57B1/6J x T stock mouse fetuses to evaluate for induced somatic changes in the genes of the coat pigment cells.*	Bayer AG	16753	Yes	No	Yes (1) [BR 051/045]	Bayer CropScience AG	A6.6.5
Hermann, G.	1979	*Fish toxicity - Dichlofluanid = KUE 13 032 c - rainbow trout.*	Bayer AG	FF-74	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Hermann, G.	1980	*Fischtoxizitaet - Dichlofluanid = KUE 13032C - Goldorfe.*	Bayer AG	FO-288	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Holzum, B.	1991	KUE 13032 C (c n. Dichlofluanid)	Bayer AG	20589	Yes	No	Yes (1)	Bayer	A6.8.2

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		- Two-Generation Study on Rats.					[BR 051/055]	CropScience AG	
Holzum, B.	1992	KUE 13032 C (c n. Dichlofluanid) - Supplementary Two-Generation Study on Rats.	Bayer AG	21922	Yes	No	Yes (1) [BR 051/057]	Bayer CropScience AG	A6.8.2
HSE (Health & Safety Executive)	2005	EH40/2005 Workplace exposure limits.	_	ISBN 0 7176 2977 5.	No	Yes	No	HSE	Published
IPCS (International Programme on Chemical Safety)	1996	Environmental Health Criteria 187: White Spirit (Stoddard Solvent). World Health Organization, Geneva.	_	EHC 187	No	Yes	No	_	B6.5 Published
IPCS (International Programme on Chemical Safety)	2001	EHC (environmental Health Criteria 227: Fluorides. World Ehalth Organisation, Geneva. Avaiable at http://www.inchem.org/documents/ehc/ehc227 htm#1.7	_	No 227	No	Yes	No	_	_
IPCS (International Programme on Chemical Safety)	2001	Naphtha (petroleum), hydrotreated heavy. No. 1380.	_	_	No	Yes	No	_	B2.2 Published
IPCS (International Programme on Chemical Safety)	2002	Environmental Health Criteria 227: Fluorides. World Health Organization, Geneva. Available at: http://www.inchem.org/documents/ehc/ehc227 htm#1.7	_	EHC 227	_	Yes	No	_	Published
Jones, R.D.	1997	Supplemental submission to Bayer Report No. R 5832 : Technical	Miles Inc, USA	6355	No	No	Yes (2)	Bayer CropScience AG	A6.5

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		grade Dichlofluanid (Euparen VM 90): Oral dosing chronic toxicity studies on the Beagle dog. (from Christenson & Elcock)							
Jungheim, M.	2001	*Physicochemical Properties of Dichlofluanid.*	Bayer AG	N 01 /0054/00 LEV	Yes	No	Yes (2)	Bayer Chemicals AG	A3 (3.1)
Jungheim, R.	2004	*Solubility of Dichlofluanid techn.(Euparen tech) in organic solvents.*	Bayer Industry Services	A 02/0108/03 LEV	Yes	No	Yes (2)	Bayer AG	A3 (3.7)
Jungheim, R	2005	Validation of analytical methods of Dichlofluanid and impurities in technical Dichlofluanid.	Bayer Industry Services,	G 04/0043/01 LEV	Yes	No	Yes (2)	Lanxess Deutschland GmbH	A4.1
Kehrig, B.; Steffens, W.	2003a	Occupational Medical Experiences with Dichlofluanid in the FU-Plant, Dormagen	.Bayer Cropscience AG	_	No	No	Yes (2)	Bayer CropScience AG	A6.12
Kehrig, B.; Steffens, W.	2003b	Occupational Medical Experiences with Dichlofluanid in the FL-Plant, Dormagen	.Bayer Cropscience AG; Bayer AG	_	No	No	Yes (2)	Bayer CropScience AG	A6.12
Kimmerle, G.	1962	*Product KUE 13032c (=Bayer 47531).*	Bayer AG	_	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Klusacek, H.; Krasemann, R.	1986	*Thermal Stability of the agrochemical active ingredient dichlofluanid.*	Bayer AG	86/1046TA	No	No	Yes (1) [BR 051/006]	Bayer CropScience AG	A3(3.1. & 3.10)
Knopf, R.	2004	Storage Stability - JJT 3581 Dichlofluanid Solvent-based Guide Recipe.	Bayer Industry Services, Germany; Bayer AG	G03/0109 /00 UER	No	No	Yes (2)	Bayer Chemicals AG	B3 (3.7)
Kowalski, R.L.;	1989	A teratology study with	Miles, Inc., USA	R 4749	Yes	No	Yes (1)	Bayer	A6.8.1

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Clemens, G.R.; Hartnagel, R.E. Jr.		Dichlofluanid (Euparen VM 90) in the rat.					[BR 051/050]	CropScience AG	
Krohn, J.	1985	Water Solubility of DMSA.	Bayer AG	5/0050 (PC 836)	No	No	Yes (2)	Bayer CropScience AG	A3 (3.5)
Krohn, J.	1986	*Dichlofluanid - Spectra of the active ingredient.*	Bayer AG	MO-99-014857	No	No	Yes (1) [BR 051/004]	Bayer CropScience AG	A3 (3.4)
Krohn, J.	1989	Octanol/water partition coefficient of Dimethylsulfanilide (DMSA)	Bayer AG	Q5050408 (PC 835)	No	No	Yes (2)	Bayer CropScience AG	A3 (3.9)
Krohn, J	1999	Density and vapour pressure of Dichlofluanid-DMSA	Bayer AG	14 660 0961	No	No	Yes (2)	Bayer CropScience AG	A3 (3.2)
Kroetlinger, F.; Loeser, E.	1982	KUE 13032 C (Dichlofluanid, Euparen(R) active ingredient) - Chronic toxicological study on mice (feeding experiment over 2 years).	Bayer AG	10810	No	No	Yes (1) [BR 051/031]	Bayer CropScience AG	Non-key study
Kroetlinger, F.; Luckhaus, G.	1981	KUE 13032c: Subchronic toxicological study to ascertain the dose-time relationship in the effect on the thyroid (feeding study over 9 weeks).	Bayer AG	10132	No	No	Yes (1) [BR 051/030]	Bayer CropScience AG	A6.10
Kroetlinger, F.; Rosenbruch, M.	2003	*Dichlofluanid - Study for subacute dermal toxicity in rats.*	Bayer AG	AT00344	Yes	No	Yes (2)	Bayer Chemicals AG	A6.3.2
Kroetlinger, F.	1990	KUE 13032 C 90 VM 00670/1146 B (c.n. Dichlofluanid) - Study for acute oral toxicity in rats.	Bayer AG	19247	Yes	No	Yes (1) [BR 051/053]	Bayer CropScience AG	A6.1.1

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Kubiak, R.	1990	*Investigation of the Fate of Dichlofluanid in Grapes and Soils over a Period of Several Years.*	Landes- Lehr- Und Forschungsansta lt Für Weinbau, Gartenbau Und Landwirtschaft, Germany; Bayer AG	FM717	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Kubiak, R.	1992	Fate of two selected 14C-labelled compounds in plant and soil after repeated application. BCPC Monograph No. 53, Lysimeter Studies, of Pesticides in the Soil, pp 133-140, 1992.	_	_	_	Yes	No	_	Published
Kugler, M.	2003	*Test Report: Determination of the antimicrobial effects of Preventol A 4-S against bacteria and fungi.*	Bayer Chemicals AG	Test Report 2003-05-23	No	No	Yes (2)	Bayer Chemicals AG	A5.3.1
Lakaschus, S.; Rzepka, S.	2003	Method for the determination of residues of Dichlofluanid and DMSA in soil-Validation of the DFG Method S19 (Extended and revised version).	Dr. Specht & Partner, Chemische Laboratorien GmbH; Bayer AG	BAY-0315V (G03-0105)	Yes	No	Yes (2)	Bayer Chemicals AG	A4 (4.1-4.3)
Lehn, H.	1988a	*KUE 13032 C -Dichlofluanid - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay* in vitro.	Bayer AG	17239	Yes	No	Yes (2)	Bayer CropScience AG	A6.6.3
Lehn, H.	1988b	*KUE 13032 C - Dichlofluanid - Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay* in vitro.	Bayer AG	17127	Yes	No	Yes (1) [BR 051/047]	Bayer CropScience AG	A6.6.6

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Leser, K.H.	1993a	*KUE 13032 C (Dichlofluanid) - Study on chronic toxicity and carcinogenicity in Wistar rats (administration in food over 105 weeks).*	Bayer AG	22313	Yes	No	Yes (1) [BR 051/059]	Bayer CropScience AG	A 6.5/6.7
Leser, K.H.	1993b	*KUE 13032 C (Dichlofluanid) - Study for oncogenicity in B6C3F1 mice (administration in feed over 2 years).*	Bayer AG	22679	Yes	No	Yes (1) [BR 051/061]	Bayer CropScience AG	A6.7
Leser, K.H.	1994a	*KUE 13032 C (c.n. Dichlofluanid) - Study on chronic toxicity and carcinogenicity in Wistar rats (administration in food over 105 weeks). Amendment to Bayer Report No. 22313*	Bayer AG	22313 A	Yes	No	Yes (1) [Amend-ment to BR 051/059]	Bayer CropScience AG	A 6.5/6.7
Leser, K.H.	1994b	*KUE 13032 C (c.n. Dichlofluanid) - Study for oncogenicity in B6C3F1 mice (administration in feed over 2 years). Amendment to Report No.22679*	Bayer AG	22679 A	Yes	No	Yes (1) [Amend-ment to BR 051/061]	Bayer CropScience AG	A6.7
Loeser, E.	1968	BAY 47531 - Chronic toxicological studies on rats.	Bayer AG	885	No	No	Yes (1) [BR 051/014]	Bayer CropScience AG	Non-key study
Loeser, E.	1969a	*Chronic toxicity studies on dogs (two-year feeding experiment).*	Bayer AG	1653	No	No	Yes (1) [BR 051/016]	Bayer CropScience AG	Non-key study
Loeser, E.	1969b	BAY 47531 - Generation study on rats.	Bayer AG	1399	No	No	Yes (1) [BR 051/015]	Bayer CropScience AG	Non-key study
Lorke, D.; Loeser, E.	1966	*Bayer 47531 - Subchronic*	Bayer AG	_	No	No	Yes (1)	Bayer	Non-key study

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		toxicological study on dogs.					[BR 051/013]	CropScience AG	
Lorke, D.	1964	Report of 4-months feeding tests on rats with active ingredient Bayer 47531.	Bayer AG	_	No	No	Yes (2)	Bayer CropScience AG	A6.4.1
Machemer, L.	1974a	*KUE 13032 c (active ingredient of Euparen) - dominant lethal study to investigate mutagenic potential.*	Bayer AG	4424	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Machemer, L.	1974b	*KUE 13032 C: studies for embryotoxic and teratogenic effects on rats following oral administration.*	Bayer AG	4668	No	No	Yes (1) [BR 051/017]	Bayer CropScience AG	Non-key study
Machemer, L.	1987	Euparen: Epicutaneous testing for skin allergenic potential to volunteers.	Bayer AG		No	No	Yes (1) [BR 051/043]	Bayer CropScience AG	A6.12
Mawdesly-Thomas L.E.	1969	Pathology Report of the chronic toxicity of compound BAY 47531 in rats. Addendum to Report No. 885 of the Institute for Toxicology of Farbenfabriken Bayer AG (Loeser, 1968)	Huntingdon Research Centre, UK; Bayer AG	3045/69/471	No	No	Yes (2)	Bayer CropScience AG	Non-key study
Mawdesly-Thomas, L.E.; Newman, A.J.; Spicer, E.J.F.;	1969	Pathology Report of BAY 47531 Two Year Dog Study (Addendum to Report No 1653, from Loeser, 1969a)	Huntingdon Research Centre, UK; Bayer AG		*No*	No	Yes (2)	Bayer CropScience AG	Non-key study
Mihail, F.	1990	*KUE 13032 C 90 VM - Investigations of acute oral toxicity in rats.*	Bayer AG	18627	No	No	Yes (2)	Bayer CropScience AG	A6.1.1
Mueller, G.	1998a	DMSA Biodegradation.	Bayer AG	689A/97O	Yes	No	Yes (2)	Bayer Chemicals AG	A7.1.1.2.1

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Mueller, G.	1998b	DMSA Toxicity to Bacteria.	Bayer AG	689A/97B	Yes	No	Yes (2)	Bayer AG	A7.4.1.4
Mueller, G.	1999	*Investigation of the ecological properties of DMSA. (DMSA biodegradation)*	Bayer AG	770A/98	Yes	No	Yes (2)	Bayer Chemicals AG	A7.1.1.2.1
Mueller, G.	2001	*Preventol A 4-S - Toxicity to Bacteria.*	Bayer AG	1135 A/01 B	Yes	No	Yes (2)	Bayer Chemicals AG	A7.4.1.4
Ochs, U.; Heyne, R.	2004	*Occupational Medical Experiences with Dichlofluanid.*	Bayer Industry Services		No	No	Yes (2)	Bayer Chemicals AG	A6.12
OECD (Environment Directorate, Paris)	2003	Emission Scenario Document for Wood Preservatives. OECD Series on Emission Scenario Documents No. 2 (Parts 1 & 2)	_	_	No	Yes	No	OECD	Published
Olf, G.	2001	*Surface Tension, Physical-chemical Properties of Dichlofluanid.*	Bayer AG	01/008/03	Yes	No	Yes (2)	Bayer Chemicals AG	A3 (3.13)
Pallett, K. ; Gosch H.	2004	Effects of Dichlofluanid on the phytotoxicity of non-target plants: seedling, emergence and seedling growth test.	Bayer CropScience GmbH	SE04/004	Yes	No	Yes (2)	Bayer Chemicals AG	A7.5.1.3
Parish, H.M.	1982	*Embryotoxicity study in rabbits with oral application of KUE 13032 C (Dichlofluanid; a.i. of Euparen).*	Institute Of Toxicology, Germany	R 2415	Yes	No	Yes (1) [BR 051/034]	Bayer CropScience AG	A6.8.1
Pauluhn, J.	1982	KUE 13032 C (Dichlofluanid) - Studies to determine a primary irritant effect on the skin and mucous membranes.	Bayer AG	Study No: T 9010818	No	No	Yes (1) [BR 051/033]	Bayer CropScience AG	A6.1.4

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Pauluhn, J.	1988	*KUE 13032 C 90 VM 1146 B (Dichlofluanid) - Study for acute inhalation toxicity to the rat according to OECD Guideline No. 403.*	Bayer AG	16493	Yes	No	Yes (2)	Bayer CropScience AG	A6.1.3
Pauluhn, J.	2000	*Preventol A 4-D (Dichlofluanid) – Study on acute inhalation toxicity in rats according to OECD No. 403.*	Bayer AG	PH 30129	Yes	No	Yes (2)	Bayer Chemicals AG	Non-key study
Riegner, K.	1992	*Method for the determination of Dichlofluanid in air.*	Bayer AG	RA-620/92 (00293)	No	No	Yes (2)	Bayer CropScience AG	A4(4.1-4.3)
Ritter, A.	1989a	Toxicity of Euparen M WG 50 to Scenedesmus subspicatus (OECD Algae Growth Inhibition Test).	RCC Umweltchemie AG, Switzerland; Bayer AG	235260	Yes	No	Yes (2)	Bayer CropScience AG	A7.4.1.3
Ritter, A.	1989b	*Influence of Dichlofluanid on the reproduction of Daphnia magna.*	RCC Umweltchemie AG, Switzerland; Bayer AG.	232841	Yes	No	Yes (1) [BR 051/082]	Bayer CropScience AG	A7.4.3.4
Roper, C.S.; Sherratt, R.	2004	*The* in vitro *percutaneous absorption of radiolabelled Dichlofluanid in a wood protection test product through human skin.*	Inveresk Research, UK; Bayer AG	23181	Yes	No	Yes (2)	Bayer Chemicals AG	B6.4
Rosenfeldt, F.	1989	*Dissociation constant of DMSA*	Bayer AG	Q5110418 (PC 839)	No	No	Yes (2)	Bayer AG	A3 (3.6)
Schneider, J.	2001	*Melting Point of KUE 13032C (Dichlofluanid).*	Bayer AG	14 0054 1054	Yes	No	Yes (2)	Bayer Chemicals AG	A3 (3.1)
Schneider, J.	2002	*Partition Coefficient in Octanol-*	Bayer	14 0032	Yes	No	Yes (2)	Bayer Chemicals	A3 (3.5, 3.6 & 3.9)

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		Water, Water Solubility and pKa Value in Dependence on Temperature of KUE 13032 C (Dichlofluanid).	Cropscience AG	1074				AG	
Schoknecht, U., W. Horn & O. Jann	2002	Biocides Emissions from Materials. Methods for the assessment of substances.	Materialien. Bundesanstalt für Materialforschung und prüfung (BAM). Umweltbundesamt (UBA), Berlin.	UFA-FB 29967410	No	Yes	No	_	B7.1
Scholz, K.	1985	*Leaching characteristics of Dichlofluanid (Euparen) aged in soil.*	Bayer AG	PF 2477	No	No	Yes (1) [BR 051/059]	Bayer CropScience AG	A7.2.3.2
Scholz, K.	1987a	*Degradation of Dichlofluanid in Water-Sediment systems.*	Bayer AG	2800 (IM 1257)	No	No	Yes (2)	Bayer CropScience AG	A7.1.2.2.2
Scholz, K.	1987b	*Leaching characteristics of Dichlofluanid (Euparen) with various modes of application.*	Bayer AG	PF 2799	No	No	Yes (1) [BR 051/071]	Bayer CropScience AG	A7.2.3.2
Scholz, K.	1987c	*Metabolism of [ring-UL-14C] dichlofluanid (Euparen) in soil under anaerobic conditions.*	Bayer AG	PF 2894	No	No	Yes (1) [BR 051/070]	Bayer CropScience AG	A7.2.2.4
Scholz, K.	1988	*Metabolism of [benzene-ring-UL-14C] dichlofluanid (Euparen) in soil under aerobic conditions.*	Bayer AG	PF 2985	No	Yes	Yes (1) [BR 051/072]	Bayer CropScience AG	A7.2.1
Scholz, K.	1997	Aerobic degradation of Dichlofluanid in Water-Sediment.	Bayer AG	4319 (MR-948/97)	Yes	No	Yes (2)	Bayer CropScience AG	A7.1.2.2.2

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Schrage	1995	*Preventol - for mould-resistant surface coatings. Test Report Preventol A 4-S.*	Bayer AG		No	No	Yes (2)	Bayer Chemicals AG	Non-key study
Schultz, C.	2003a	Paint Systems - Dichlofluanid, DMSA - HPLC method.	Bayer AG	Method No: 2301-0289901-03E	No	No	Yes (2)	Bayer AG	B4 (4.1)
Schultz, C.	2003b	Validation Report.	Bayer AG	Method No: 2301-0289901-03E	No	No	Yes (2)	Bayer AG	B4 (4.1)
Shell Chemicals	2003	Material Safety Data Sheet "Shellsol D60" (version 1.2)	–	–	No	Yes	No	–	B2.2 B3 (3.2)
Shiotsuka, R.N.	1986	*Acute inhalation toxicity study with Preventol A 4-S Dust in rats.*	Mobay Corp., USA Bayer AG	763	Yes	No	Yes (1) [BR 051/040]	Bayer Chemicals AG	Non-key study
Shirasu, Y.; Moriya, M.; Watanabe, T.	1978	*Mutagenicity study of Euparen on bacterial systems.*	Agricultural Chemicals Inst., Japan		No	No	Yes (2)	Bayer Chemicals AG	Non-key study
Sommer, H.	2001a	*Estimation of the Adsorption Coefficient (Koc) of Dichlofluanid on soil using High Performance Liquid Chromatography (HPLC).*	Bayer AG	MR-010/01	Yes	No	Yes (2)	Bayer Chemicals AG	A7.1.3
Sommer, H.	2001b	Estimation of the Adsorption Coefficient (Koc) of DMSA on Soil using High Performance Liquid Chromatography (HPLC).	Bayer AG	MR-011/01	Yes	No	Yes (2)	Bayer Chemicals AG	A7.1.3
Steinhauer, S.	2003	Validation of an analytical method (analogous to DFG Method W5) for the determination of residues of	Dr. Specht & Partner, Chemische	BAY-0208V (G02-0060, BCH-MPP-	Yes	No	Yes (2)	Bayer Chemicals AG	A4 (4.1-4.3)

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		N-N-Dimethyl-N`-Phenylsulphamide (DMSA) in drinking and surface water.	Laboratorien GmbH; Bayer AG	2002-14)					
Stubblefield, W.A.	1986a	*Acute Oral LD50 of Preventol A4-S to Bobwhite Quail.*	Mobay Corp., USA; Bayer AG	770	Yes	No	Yes (1) [BR 051/078]	Bayer Chemicals AG	A7.5.3.1.1
Stubblefield, W.A.	1986b	Subacute dietary LC50 of Preventol A4-S to Bobwhite Quail.	Mobay Corp., USA; Bayer AG	773	Yes	No	Yes (1) [BR 051/080]	Bayer Chemicals AG	A7.5.3.1.2
Stubblefield, W.A.	1986c	*Subacute dietary LC50 of Preventol A4-S to Mallard Ducks.*	Mobay Corp., USA; Bayer AG	775	Yes	No	Yes (1) [BR 051/079]	Bayer Chemicals AG	A7.5.3.1.2
Swigert, J.	1986a	*Acute flow-through toxicity of Preventol A 4-S to Rainbow Trout (Salmo gairdneri).*	ABC Laboratories Inc., USA; Bayer AG	779	Yes	No	Yes (1) [BR 051/077]	Bayer Chemicals AG	A7.4.1.1
Swigert, J.	1986b	Acute flow-through toxicity of Preventol A 4-S to Bluegill Sunfish (Lepomis macrochirus).	ABC Laboratories Inc., USA; Bayer AG	780	Yes	No	Yes (1) [BR 051/076]	Bayer Chemicals AG	A7.4.1.1
Thyssen, J.	1978	*Preventol A 4 - Irritation of skin and mucosa.*	Bayer AG		No	No (2)	Yes	Bayer Chemicals AG	Non-key study
Treckmann, D.I.	1994	*Vapour Pressure - Dichlofluanid (Euparen).*	Bayer AG	93/237 (PC 184)	Yes	No	Yes (2)	Bayer CropScience AG	A3 (3.2)
van Ginkel, G.G.; Stroo, C.A.	2000	Biodegradability of Preventol A4S in the Closed Bottle Test.	Akzo Nobel NL;Bayer AG	CGS-ENV F00057 T 00003 C	Yes	No	Yes (2)	Bayer Chemicals AG	A7.1.1.2.1
Veith, M.	2001	Analytical results of five representative batches of Euparen, techn. (Dichlofluanid techn.).	Bayer AG	2001-08-10	No	No	Yes (2)	Bayer CropScience AG	Confidential Annex only

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No in Doc III-A or B / Confidential Annex / Non-key study / Published
Verdam, B., Loch, J.P.G. & Maaren, van H.L.J.	1988	Bestrijdingsmiddelen in grondwater onder kwetsbare bodentypen.	National Institute of Public Health and Environmental Protection (RIVM)	728473001	No	Yes	No	_	Published
Vince A.A.; Spicer, E.J.F.	1971	Pathology Report of BAY 47531 - Generation experiments in rats, Bayer study 1399 (from Loeser, 1969b)	Bayer AG	1399	No	No	Yes (1) [BR 051/015]	Bayer CropScience AG	Non-key study
Voelkner, W.	1989	Chromosome aberration assay in bone marrow cells of the Chinese hamster with KUE 13032 C.	Cytotest Cell Research GmbH & Co.	R 4867	Yes	No	Yes (2)	Bayer CropScience AG	A6.6.4
Weber, H.	1985	*(Phenyl-U-^{14}C)Dichlofluanid - Biokinetics Part of general metabolism study on rats.*	Bayer AG	PF 2391	No	No	Yes (1) [BR 051/037]	Bayer CropScience AG	A6.2
Weber, H.; Patzschke, K.; Wegner, L.A.	1977	*(^{14}C) Dichlofluanid (active ingredient of Euparen) – Biokinetic study on rats.*	Bayer AG	7081	No	No	Yes (1) [BR 051/018]	Bayer CropScience AG	A6.2
Weber, H.; Dressler, H.F.	1981	*Effect of subchronic KUE 13032c (Euparen active ingredient) administration on the thyroid function in male rats. Part of Bayer study No 10132*	Bayer AG	9862	No	No	Yes (1) [BR 051/029]	Bayer CropScience AG	A6.10
Weeren, R.D.; Pelz, S.	1999	Validation of an analytical method (analogous to DFG method W 5) for the determination of residues of Dichlofluanid in drinking and surface water.	Dr. Specht & Partner, Chemische Laboratorien GmbH; Bayer AG	BAY-9904V (M5893/99)	Yes	No	Yes (2)	Bayer Chemicals AG	A4 (4.1-4..3)
Wegener, R.	2004	Testing of the preservative (JJT 3581) according OECD guideline	Materialprüfung samt des Landes	31/03/7423/ 01	No	No	Yes (2)	Bayer Chemicals AG	B7.1

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		for testing chemicals (Proposal for a new guideline I). Estimation of emission from preservative - treated wood to the environment: Laboratory method for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground.	Brandenburg						
Wilmes, R.	1982a	Properties of Pesticides in Water, Hydrolytic Stability - Euparen (Dichlofluanid).	Bayer AG	MR 86003	No	No	Yes (2)	Bayer CropScience AG	A7.1.1.1.1
Wilmes, R.	1982b	Orientating Light Stability - Euparen (Dichlofluanid).	Bayer AG	MR 86002 (WLF OL-032)	No	No	Yes	Bayer CropScience AG	Non-key study
Wittmann, O.	2004	*Dichlofluanid technical, Preventol A 4-S, Prvententol A 4-D, Preventol A 4-F, Corrosion Characteristics, Packaging Materials.*	Bayer AG	_	No	No	Yes (2)	Bayer Chemicals AG	A3 (3.17)
Wittmann, O.; Schmidt, K.	2001	Preventol A 4-S (Dichlofluanid) - Synthesis.	Bayer AG		No	No	Yes (2)	Bayer Chemicals AG	Confidential Annex only