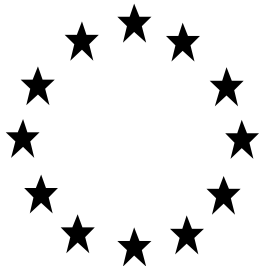
Directive 98/8/EC concerning the placing of biocidal products on the market

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

Assessment Report



Cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO)

Product-type 8 (Wood preservatives)

22 February 2008

Annex I – Austria

Cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) (PT 8)

Assessment Report

Finalised in the Standing Committee on Biocidal Products at its meeting on 22 February 2008 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 Cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) 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 or IA to the Directive.

K-HDO (CAS no. 66603-10-9) was notified as an existing active substance, by Dr. Wolman GmbH (Sinzheim, Germany), hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[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 7(1) of that Regulation, Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for K-HDO as an active substance in product-type 8 was 28 March 2004, in accordance with 9(2) of Regulation (EC) No 1451/2007.

On 29 March 2004, the Austrian Competent Authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 27 September 2004.

On 22 March 2006, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 27 March 2006. The competent authority report included a recommendation for the inclusion of K-HDO in Annex I to the Directive for product-type 8.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 26 April 2006. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

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

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

On the basis of the final competent authority report, the Commission proposed the inclusion of K-HDO in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 22 February 2008.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 22 February 2008.

1.2. Purpose of the assessment report

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

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

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

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

The overall conclusion from the evaluation is that it may be expected that there are products containing K-HDO for the product-type 8, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

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

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

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

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

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

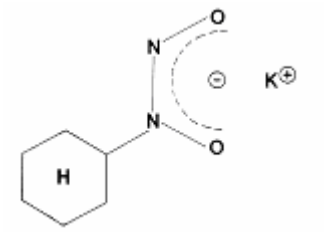
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

The identity of the active substance Cyclohexylhydroxydiazene 1-oxide, potassium salt can be summarised as follows:

Table 2.1. Identity of the active substance

CAS-No.	66603-10-9
EINECS-No.	not attributed
Other No. (CIPAC, ELINCS)	not attributed
IUPAC Name	Cyclohexylhydroxydiazene 1-oxide, potassium salt
Common name, synonyma	synonyma: (N-cyclohexyldiazenium-dioxy)-potassium, K-HDO, K-NCH
Molecular formula	C6H11KN2O2
Structural formula	
Molecular weight [g/mol]	182.3

K-HDO is manufactured as a 30%w/w aqueous solution ("active substance as manufactured"). When disregarding the water, the active substance consists of 97.7%w/w K-HDO and 2.3 % w/w impurities. Besides, several tests were conducted with purified KHDO ("purified active substance", 99.8%w/w KHDO monohydrate)

The active substance evaluated for inclusion into Annex I of the Biocidal Products Directive 98/8/EC corresponds to the active substance as manufactured excluding any water.

The purified active substance Cyclohexylhydroxydiazene 1-oxide, potassium salt (99.8 %w/w) is highly flammable; it is neither oxidising nor explosive, and it is not volatile. Since the active substance is only manufactured as 30% aqueous solution, it is not flammable due to the high water content; the active substance as manufactured is thermally stable up to ~200°C. In the case of combustion, CO_2/CO, H_2O and NO_x will be generated.

In conclusion, no hazards can be identified for the physico-chemical properties of the active substance as manufactured.

The identity, physical-chemical properties and the methods of analysis are furthermore listed in Appendix I to the assessment report and details are presented and discussed within the Competent Authority Report.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

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

2.1.3. Classification and Labelling

No current classification is available. The proposed classification and labelling of the active substance is as follows:

Classification:	F; R11 T; R25 Xi; R38-41 R52-53
Hazard symbol:	F, T
Indication of danger:	highly flammable, toxic, irritant
Labelling symbol:	
Risk phrases:	R: 11-25-38-41-52/53
Safety phrases:	S: 2-9-13-26-36/37/39-45-46-61

The proposed classification and labelling of the active substance as manufactured (K-HDO as 30%w/w aqueous solution) is as follows:

Classification:	Xn; R22 Xi; R38-41
Hazard symbol:	Xn
Indication of danger:	harmful, irritant
Labelling symbol:	
Risk phrases:	R: 22-38-41
Safety phrases:	S: 2-13-26-36/37/39

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

The toxicological data package for Cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) comprises acute toxicity tests including skin and eye irritation and sensitization tests, toxicokinetics, genotoxicity tests and repeated dose toxicity tests up to a 96 day gavage study. The chronic, carcinogenicity and reproductive toxicity tests were carried out with Cyclohexylhydroxydiazene 1-oxide, copper salt (Cu-HDO) and the respective results were read across to K-HDO on an equimolar basis. The read across arguments were essentially based on the very similar toxicokinetics of Cu-HDO and K-HDO and on the fact that the HDO anion from Cu-HDO and K-HDO is structurally identical and the K^+ ion is devoid of toxic properties when applied via diet at reasonable doses.

The only critical endpoints that resulted from the studies submitted for K-HDO were the skin irritation and the severe effects on the eye of the 30% aqueous solution. When K-HDO was applied via food no effect was observed up to the highest dose applied of 724 mg/kg bw day for 42 days. However the highest dose for which histological analysis is available is for the gastro-intestinal tract 90 mg/kg bw day within a 28 day feeding study and for all other tissues 50 mg/kg bw day within a 96 day gavage study. The acute clinical effects of K-HDO with gavage application above 25 mg/kg bw day were considered of minor relevance for risk assessment since they were attributed to the bolus effect of the K^+ ion disturbing the normally rigidly controlled K^+ homeostasis.

The toxicological targets of Cu-HDO were the gastro-intestinal tract, the liver and the kidney apparent also as histological effects. The lowest LOAEL was 33 mg/kg bw within the 2-year rat study. The fact that these targets were not observed with K-HDO might be due to the slow dissociation of Cu-HDO leading to increased cellular uptake of copper to cytotoxic levels or due to the fact that K-HDO was not histologically analysed at comparable long term doses. However the overall results indicate that under the assumption of comparable toxicokinetics Cu-HDO is not less toxic compared to K-HDO. Thus the NOAEL of 6 mg/kg bw day from the 2-years rat study with Cu-HDO was considered to be a sufficiently conservative value for estimating the 2-year NOAEL of K-HDO by equimolar read across leading to 6.25 mg/kg bw day K-HDO.

From the in vitro dermal absorption study a tier 1 and a tier 2 estimate for dermal absorption rate were derived. In order to understand the impact of the two interpretations the risk characterisation is calculated with both values (18.7% and with 8%) resulting in 2 sub-tiers. For product authorisation the 18.7% value should be used as tier 1 assessment whereas the 8% value could be used for higher tier refinements.

2.2.1.2. Effects assessment

For the assessment of daily exposure the chronic NOAEL from the 2 years study of 6.25 mg/kg bw day was used. A safety factor of 300 was required accounting for the fact that the absence of alerts for fertility effects was only deduced from the available repeated dose and developmental studies but no 2-generation study was submitted.

For the assessment of sporadic exposure situations the lowest NOAEL apparent in the sub-acute repeated dose studies was used, which was 10.2 mg/kg bw day with the rabbit developmental toxicity study. A safety factor of 100 was considered sufficient, since sporadic exposure would correspond rather to an acute than a sub-acute experiment and since the maternal effects were reversible with cessation of dosing and since sporadic low dose exposure to non-genotoxic substances is considered to be of low probability with regard to effects on fertility.

The evaluation of sub-chronic exposure scenarios was not necessary for the intended uses described within this report. However in case of future need it is proposed to use the same NOAEL as for the sub-acute exposure situations which is 10.2 mg/kg bw day from the rabbit developmental toxicity study, but apply a safety factor of 300 to account for the fact that the absence of alerts for fertility effects was only deduced from the available repeated dose and developmental studies but no 2-generation study was submitted.

2.2.1.3. Risk characterisation

Since K-HDO is produced in fully automatic and closed systems the exposure during the manufacturing of K-HDO was considered disregardable. Also during the application of K-HDO within the manufacture of wood composites the worker exposure is minimal since also this process is fully automatic. However for assessing the worst case for the latter process the potential inhalation exposure was calculated on the basis of the saturation concentration of K-HDO in air. For potential dermal exposure due to sporadic interventions with the system two assessment approaches from the TNsG on human exposure were selected. The chronic

inhalation exposure estimates were compared with the NOAEL from the 2-year study and the sporadic dermal exposure estimates were compared with the sub-acute NOAEL. In summary it can be stated that with worst case as well as with normal use assumptions the risk can be considered acceptable since the margin of exposure results far above 300.

Table 2.2.1.3.1. Primary exposure during the application of the product

	exposure scenario	estimated inhalation uptake [mg/kg bw day]	estimated dermal uptake [mg/kg bw]	estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = reference MOE	MOE = NOAEL/exposure	exposure / AEL
Filling and loading (sporadic dermal)	realistic approach 1: PPE effects, 18.6% dermal uptake	0.001	0.00077	0.002	NOAEL sub-acute 10.2	100	5178	0.02
	realistic approach 2: PPE effects, 8% dermal uptake	0.001	0.00033	0.001	NOAEL sub-acute 10.2	100	7133	0.01
Contact of workers with treated wood (sporadic dermal)	normal use 1: PPE effects, 18.6% dermal uptake	0.001	0.008	0.009	NOAEL sub-acute 10.2	100	1097	0.09
	normal use 2: PPE effects, 8% dermal uptake	0.001	0.0035	0.0046	NOAEL sub-acute 10.2	100	2242	0.04

Secondary human exposure can result from contact with K-HDO treated wood composites. The use pattern of K-HDO treated wood composites is for efficacy reasons restricted to use class 2 situations and the main applications are within roof construction and outdoor with protection to direct weathering. Use within indoor living areas with the potential of direct contact is not foreseen by the applicant and should not be intended according to the evaluation in this report. For assessing the risk of any exposure to K-HDO treated wood composites by inhalation, chronic inhalation of evaporated K-HDO indoors by adult and by children was calculated based on the saturation concentration of K-HDO in air. This risk was considered acceptable even for tier 1 assumptions.

Table 2.2.1.3.2.: Secondary exposure by chronic inhalation of volatile residues indoors

exposure scenario		estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	acceptable MOE = assessment factor	MOE = NOAEL/ exposure	exposure / AEL
Chronic inhalation of volatile residues indoors by adult	Tier 1 a.s. at saturation concentration, inhalation rate = 1.25 m3/h, 18 hours exposure; 60 kg bw	0.0028	NOAEL chronic 6.25	300	2232	0.13
Chronic inhalation of volatile residues indoors by infant	Tier 1 a.s. at saturation concentration, inhalation rate = 0.22 m3/h, 18 hours exposure; 10 kg bw	0.0029	NOAEL chronic 6.25	300	2155	0.14

The second type of exposure scenarios that could be relevant for K-HDO treated wood composites is sporadic or daily processing of wood composites by professionals or by general public. These exposure scenarios were based on the calculations described in the TNsG on human exposure. In summary the assessment resulted in an acceptable risk only for professionals using gloves. Therefore it is recommend not marketing K-HDO treated wood composites to general public as long as no exposure study is available that reliably demonstrates that the transfer of K-HDO from treated wood panels to hands of workers processing the treated wood is significantly below the assumptions within this assessment.

Table 2.2.1.3.3. Secondary exposure during the processing of K-HDO treated wood composites

exposure scenario	estimated inhalation uptake [mg/kg bw day]	estimated dermal uptake [mg/kg bw]	estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = reference MOE	MOE = NOAEL/exposure	exposure / AEL
tier 2a general public no PPE, 18.6% dermal absorption	0.0004	0.066	0.066	NOAEL sub-acute 10.2	100	154	0.65
	0.0024	0.066	0.068	NOAEL chronic 6.25	300	91	3.28
tier 2b general public no PPE, 8% dermal absorption	0.0004	0.029	0.029	NOAEL sub-acute 10.2	100	348	0.29
	0.0024	0.029	0.031	NOAEL chronic 6.25	300	200	1.50
tier 3a professionals PPE, 18.6% dermal absorption	0.0004	0.008	0.008	NOAEL sub-acute 10.2	100	1201	0.08
	0.0024	0.008	0.011	NOAEL chronic 6.25	300	595	0.50
tier 3b professionals PPE, 8% dermal absorption	0.0004	0.0035	0.004	NOAEL sub-acute 10.2	100	2640	0.04
	0.0024	0.0035	0.006	NOAEL chronic 6.25	300	1059	0.28

(1) PPE … personal protective equipment (gloves)

Finally also the risk from "acute oral ingestion by infant chewing wood" was assessed. This calculation indicated an unacceptable risk for infants, which confirms that the use of K-HDO treated wood has to be restricted to applications where biocidal treatment is unavoidable (e.g. construction) but definitely excludes indoor living areas applications which would otherwise allow access of infants to the treated wood composites.

Table 2.2.1.3.4. Acute oral ingestion by infant by chewing wood composites

exposure scenario		estimated oral uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	acceptable MOE = assessment factor	MOE = NOAEL/ exposure	exposure / AEL
Acute oral ingestion by infant by chewing wood	Tier 1 100% of a.s. extracted from 4x4x1cm treated wood composite; 10 kg bw	4.13	NOAEL sub-acute 10.2	100	2	40.49
	Tier 2 max 10% of a.s. extracted	0.413	NOAEL sub-acute 10,2	100	25	4.05

Furthermore Member States should be aware that the waiving of the 2-generation study was accepted based on scientific arguments that are negligible exposure and no critical effects with respect to fertility in the available toxicity studies.

2.2.2. Environmental Risk Assessment

2.2.2.1. Aquatic compartment

Exposure during manufacturing of the biocidal product Xyligen 30F (corresponds to the production of K-HDO) to the aquatic environment is assumed to be negligible, since the manufacturing process takes place in an industrial, entirely closed system. Because application of K-HDO occurs only during the manufacturing of wood composites within a closed system, environmental exposure of K-HDO is not expected.

Treated wood (i.e. wood based panels such as particle boards for use in hazard class 2) will be stored under cover after treatment and is foreseen to be used indoors or outdoors under roof, fully protected from the weather.

Therefore a contamination of the aquatic compartment during storage and utilisation is negligible.

2.2.2.2. Atmosphere

No abiotic effects for the air compartment could be identified: Due to the low volatilisation potential (p_{vp} < 10^{-6} hPa at 20°C, $H_{calculated}$ = 4.4 · 10^{-11}·kPa m^3/mol) and the fast photo – oxidative degradation in air (DT_{50} = 3.7 hours or 11.2 hours, respectively) the concentration of K-HDO expected in air is not significant; an accumulation of K-HDO in the air and contamination by wet or dry deposition is not to be expected. Hence, no relevant exposure of the air compartment is expected. In all, no predictable risk for the air compartment could be identified.

2.2.2.3. Terrestrial Compartment

Exposure during manufacturing of the biocidal product Xyligen 30F (corresponds to the production of K-HDO) to the terrestrial environment is assumed to be negligible, since the manufacturing process takes place in an industrial, entirely closed system. Application of K-HDO occurs only during the manufacturing of wood composites and within a closed system, therefore exposure of K-HDO to the terrestrial compartment is not expected. Treated wood will be stored under cover after treatment so that no wood preservative can reach the terrestrial environment. Wood-based panels such as particle boards, equipped with fungicides like Xyligen 30F, are used in use class 2 situations (inside, outside under roof, fully protected from the weather). Outside use of wood-based panels must not occur without protection against direct weathering (additional coatings). These coatings form a barrier and prevent any leaching. A contamination of the terrestrial compartment during production, storage and utilisation can therefore be excluded.

2.2.2.4. Non Compartment Specific Effects Relevant to the Food Chain (Secondary Poisoning)

Since no analytical methods and no toxicological risk assessment for K-HDO contamination in food and feeding stuff was provided the use of K-HDO treated wood composites must exclude applications that may lead to contact with food and feeding stuff and contamination thereof. However such applications were not foreseen by the applicant anyway. In case that such contact should occur despite the above-mentioned requirements and assumptions, there is no risk of accumulation in the food chain according to the BCF of K-HDO (log BCF: - 0.87). Thus secondary poisoning can be excluded.

2.2.2.5. PBT Assessment

Persistence:

K-HDO is not readily biodegradable. In an inherent test it showed 98% elimination after 28 days. 57% of that elimination took place within the first three hours, which indicates elimination due to adsorption. The submitted simulation test was not sufficiently documented for a proper evaluation.

It is not possible to evaluate the persistence in marine or fresh water at this stage of the risk assessment.

Bioaccumulation:

BCF_{fish} = 0.134 L/kg wwt.

The B-criterion is not met.

Toxicity:

The chronic NOEC values for freshwater species are 0.47 mg/L for invertebrates

and 3.75 mg/L for algae

Endocrine disrupting effects and CMR effects:

No specific test for potential endocrine disruption and no 2-generation study were carried out. However within the sub-acute, sub-chronic, chronic and carcinogenicity, developmental toxicity and mutagenicity studies there is no evidence for endocrine disruption or for CMR effects.

The T-criterion is not met.

Conclusion: K-HDO does not meet the PBT criteria.

2.2.3. List of endpoints

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

3. DECISION

3.1. Background to the Decision

On the basis of the proposed and supported uses and the evaluation conducted as summarised in this assessment report, it can be concluded that K-HDO fulfils under the conditions listed in chapter 2.2 the requirements laid down in Article 5 (1) (b), (c), and (d) of Directive 98/8/EC. K-HDO is proposed to be included in Annex I of the Directive.

The Annex I - entry should, however, be restricted to the conditions described below (3.2.) and for product authorization the elements described below (3.3.) should be respected.

3.2. Decision regarding Inclusion in Annex I

The active substance Cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8, subject to the following specific provisions.

Common name:	K-HDO
IUPAC name:	Cyclohexylhydroxydiazene 1-oxide, potassium salt
CAS name:	Diazene, cyclohexylhydroxy-, 1-oxide, potassium salt
CAS No.:	66603-10-9
EC No.:	not attributed

Minimum degree of purity of the active substance: 977 g/kg

This entry shall also cover the hydrated forms of K-HDO.

Specific provisions

When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

Member States shall ensure that authorisations are subject to the following conditions:

(1) In view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 5 and Annex VI.

(2) In view of the assumptions made during the risk assessment, products must be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means.

(3) In view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.

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

a) Minimum degree of purity of the active substance (see 3.2.):

The active substance Cyclohexylhydroxydiazene 1-oxide, potassium salt should have a minimum purity of 977 g/kg. In case the active substance should be manufactured as aqueous solution with a K-HDO content above 31%w/w, provision f) 9 has to be considered.

b) Nature and maximum content of certain impurities:

The nature and maximum content of the impurities have been specified.

c) Product type (see 3.2.):

K-HDO is restricted to the application as wood preservative (product type 8) for the protection of wood composites.

Justification: Other types of applications of KHDO would require a different technology for which no human or environmental risk assessment was submitted; furthermore their efficacy would have to be sufficiently demonstrated.

d) Manner and area of use (see 3.2.):

The production and application of K-HDO is restricted to industrial fully automatic and closed systems practically excluding direct exposure to workers and the environment. This implies also that the tanks, containers and the technical apparatuses for the production and application of K-HDO must not be cleaned and that appropriate personal protective equipment including daily new gloves is used.

Justification: The human risk assessment is carried out with the assumptions of very strict exposure control by industrial fully automatic and closed systems. Different production or application systems could result in higher human exposure, which would need to be evaluated for acceptability in terms of risk to workers. In order to assure that the environmental risk is negligible the applicant stated that industrial production and application is a closed process that practically excludes environmental exposure and that cleaning of tanks, containers and technical apparatuses is not part of normal work routine.

e) Designation of categories of users: industrial user (see 3.2.)

f) Other particular conditions:

1) The application rate of K-HDO within particle boards should range between minimum 0.3% (w/w) K-HDO / dry particles and maximum 2.6 kg K-HDO /m^3 wood composite.

Justification: Based on the data submitted 0.3% (w/w) K-HDO/dry particle (corresponding to 1.6 - 2.2 kg K-HDO/ m^3 dry particle boards with a density range of

600 to 800 kg/m³) is the minimum concentration to guarantee sufficient efficacy; 2.6 kg K-HDO/m^3 as the maximum concentration of the intended uses was the basis for the risk assessment. A lower concentration might result ineffective and a higher concentration might result in an unacceptable risk.

2) Authorisation of K-HDO containing products to be applied with wood composites other than particle boards will require a demonstration of sufficient efficacy and of an acceptable risk for human and environmental exposure.

Justification: The efficacy data submitted were only sufficient to support the use with particle boards but not with other wood composites like oriented strand board, plywood or laminated veneer lumber. Different wood composites could for efficacy reasons require higher application rates that could affect the risk for workers and the general public. Different wood composites could also be intended for different use patterns that need to be evaluated for acceptability in terms of human and environmental risks.

3) The use of K-HDO treated wood composites should be restricted to at the highest use class 2 situations in which wood – based products are under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting.

Justification: These were the assumptions for the environmental risk assessment. If these conditions are not met a new environmental hazard and risk assessment has to be carried out resulting in an update of the Annex I entry e.g. for use class 3 and higher it might be necessary to provide data demonstrating that surface coating is effective as a measure to avoid environmental exposure.

4) It is recommended to limit the use of K-HDO treated wood composites to the minimum necessary and label it exclusively for use class 2 situations.

Justification: K-HDO is a fungicide and not effective as insecticide. According to table 5.2 of the OECD "Emission Scenario Document for Wood Preservatives, Part 2", use class 1 specifies only insects as biological agents. Therefore and since article 3.7 of the BPD aims to foster the proper use of biocides, which involves limiting the use of biocides to the minimum necessary and which is in line with the European sustainability policy and with the precautionary principle only wood preservatives containing exclusively insecticides should be labelled for use class 1 applications.

5) K-HDO treated wood composites must not be used for indoor living areas with potential of direct contact (see 3.2.)

Justification: The assessment for the exposure scenario "infant chewing wood composite" indicates an unacceptable risk. Therefore wood composites treated with biocides have to be restricted to applications where biocidal treatment is unavoidable (e.g. construction) but definitely excludes indoor living areas with potential of direct contact.

6) K-HDO treated wood composites must not come in contact with food or feedstuffs.

Justification: Since no analytical methods and no toxicological risk assessment for K-HDO contamination in food and feeding stuff was provided the use of K-HDO treated wood composites must exclude applications that may lead to contact with food and feeding stuff and contamination thereof.

7) Based on the information available in the report it is recommended to not market K-HDO treated wood panels to or to use by the general public. However, if new information on this issue is coming in for product authorisation, every Member State has to evaluate these data carefully.

Justification: The risk due to secondary chronic exposure during processing of wood is unacceptable for general public (no gloves used).

8) Member States should be aware that the 2-generation study was waived based on scientific arguments that is negligible exposure and no critical effects with respect to fertility in the available toxicity studies.

9) Before extending the applicability of K-HDO to other wood composites, use classes, use scenarios or storage conditions as well as before changing the composition of K-HDO to >31% a.s. in water additional data for one or several of the chapters analytical methods, efficacy, toxicity and ecotoxicity will be necessary and a new respective hazard and risk assessment has to be carried out demonstrating the respective acceptability.

10) The applicant stated that an additional surface treatment can be applied when there is risk of occasional wetting. Before extending the applicability of K-HDO to higher use classes, the ability of the coatings to prevent any leaching has to be supported by experimental data.

3.4. Requirement for further information

The applicant announced to provide a new wipe test for particle boards and plywood to refine the dermal exposure assessment. After submission and evaluation of this new test the necessity of the restriction to market K-HDO treated wood composites only to professionals has to be re-evaluated.

New additional data on the efficacy of K-HDO in plywood were provided by the applicant during the commenting period, which is not within the time frame designated in regulation 2032/2003, article 10. The applicant may submit further data and a new risk assessment after Annex I inclusion, the CA report and the assessment report will be amended accordingly at that time.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 5 to 8, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and

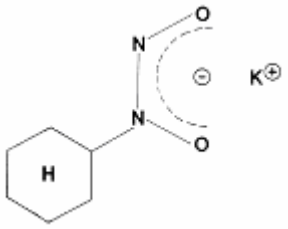
finalised in connection with any amendment of the conditions for the inclusion of Cyclohexylhydroxydiazene 1-oxide, potassium salt in Annex I to the Directive.

Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Cyclohexylhydroxydiazene 1-oxide, potassium salt
Function (*e.g.* fungicide)	Fungicide

Identity

Chemical name (IUPAC)	Cyclohexylhydroxydiazene 1-oxide, potassium salt
Chemical name (CA)	Cyclohexylhydroxydiazene 1-oxide, potassium salt ; synonyma: K-HDO, K-NCH, (N-cyclohexyldiazenium-dioxy)-potassium
CAS No	66603-10-9
EC No	not attributed
Other substance No.	not attributed
Minimum purity of the active substance as manufactured (g/kg or g/l)	The active substance (min. purity: 977 g/kg) is manufactured as min. 300g/kg aqueous solution
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Confidential data and information
Molecular formula	$C_6 H_{11} K N_2 O_2$
Molecular mass	182.3
Structural formula	

Physical and chemical properties

Melting point (purity 100 % as monohydrate)	163.1°C
Boiling point (purity 100 % as monohydrate)	decomposition before boiling point is reached
Temperature of decomposition	210°C
Appearance (purity 100 % as monohydrate)	White crystalline solid, weak odour
Relative density (purity 100 % as monohydrate)	1.431 at 20°C
Surface tension	71.4 mN/m at 20°C; (not surface active; concentration of test solution: 1 g/L)
Vapour pressure (in Pa, state temperature)	$< 10^{-6}$ hPa at 50°C and at 20°C
Henry's law constant (Pa m^3 mol^{-1})	$4.4 \cdot 10^{-11}$ kPa·m^3·mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH 10.4: 452 g·L^{-1} at 20°C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	54%(w/w) in ethylene glycol, readily soluble in ethanol, methanol and dimethylformamide
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	The representative biocidal does not include any organic solvent
Partition coefficient (log P_{OW}) (state temperature)	pH 7.2: log Pow = – 0,2 at 25°C
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 4: 1.26 d at 25°C
	pH 7: stable
	pH 9: stable
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	pk_a = 5.33
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	no absorption > 290nm
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	n.a.
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	n.a.
Flammability	active substance as manufactured (30%w/w K-HDO in water): not flammable purified K-HDO (100%w/w as monohydrate): highly flammable Autoflammability of purified K-HDO:_ No self ignition at temperatures up to melting point (163.1°C).
Explosive properties	Presents no danger of explosion in the sense of the test method

Classification and proposed labelling

with regard to physical/chemical data	Classification: F; R11 Labelling: F R: 11 S: 9
with regard to toxicological data	Classification: T; R25 Xi; R38 R41 Labelling: T R: 25-38-41 S: 2-13-26- 36/37/39-45-46
with regard to fate and behaviour and ecotoxicological data	Classification: R52/53 Labelling: R: 52-53 harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment S: 61 avoid release to the environment. Refer to special instructions/safety data sheets

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	Photometrical determination after complexation with $FeCl_3$
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Confidential data and information

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	HPLC detection after extraction
Air (principle of method and LOQ) (Annex IIA, point 4.2)	only required for volatile substances with a vapour pressure greater than 0.01 Pa
Water (principle of method and LOQ) (Annex IIA, point 4.2)	Photometrical determination after complexation with $FeCl_3$
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	---
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	---
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	---

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	Readily and complete
Rate and extent of dermal absorption:	in vitro test with human skin: Tier 1: ~ 19% after 24 hours of exposure Tier 2: ~ 8% after 10 hours of exposure
Distribution:	Plasma level below 0.1% of applied dose during the whole test period of 72 hours. Biliary excretion ~ 30 % of applied dose within 24 hours.
Potential for accumulation:	No indication for bioaccumulation
Rate and extent of excretion:	excretion primarily via urine, excretion cessing after 48 hours
Toxicologically significant metabolite	None

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	136 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 7.8 mg/l with 4 hours of exposure
Skin irritation	Irritating to skin (rabbit)
Eye irritation	Risk for serious damage to eye (rabbit)
Skin sensitization	Not sensitizing (local lymph node assay)

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	Rat/feeding: no effects Rat/gavage: acute clinical effects Cu-HDO: GI, liver, kidney
Lowest relevant oral NOAEL / LOAEL	Rat, 42 days, NOAEL > 724 mg/kg bw day Rat, 3 months, NOAEL = 25 mg/kg bw day Rat, 12 months, NOAEL = 18.7 mg/kg bw day (test carried out with Cu-HDO)
Lowest relevant dermal NOAEL / LOAEL	---
Lowest relevant inhalation NOAEL / LOAEL	Rat, 28 days (18 times), NOAEL < 0,6 mg/l

Genotoxicity (Annex IIA, point 6.6)	Ames test: no genotoxic effects
	Mouse lymphoma forward mutation assay in vitro: no mutagenic or clastogenic properties
	Micronucleus assay: no genotoxic effects

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	Rats / no oncogenic effects (test carried out with Cu-HDO) NOAEL = 6.25 mg/kg
Lowest dose with tumours	-

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	No 2-generation study is available for K-HDO or Cu-HDO. The available repeated dose studies with K-HDO and with Cu-HDO and the developmental toxicity studies with Cu-HDO do not indicate a concern for K-HDO to have an impact on reproductive organs or functions.
Lowest relevant reproductive NOAEL / LOAEL	-
Species/Developmental target / critical effect	rats and rabbits / no indications for teratogenic property (test carried out with Cu-HDO)
Lowest relevant developmental NOAEL / LOAEL	Rat (test carried out with Cu-HDO): NOAEL maternal = 30 mg/kg bw day NOAEL foetal = 100 mg/kg bw day Rabbit (test carried out with Cu-HDO): NOAEL maternal = 10 mg/kg. NOAEL foetal = 10 mg/kg

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	rats/ no clinical effect / no effect in functional observation test battery (28 day study)
Lowest relevant developmental NOAEL / LOAEL.	> 90 mg/kg bw 28 days

Medical data (Annex IIA, point 6.9)

.....	No poisoning incident known

Summary (Annex IIA, point 6.10)	AELs	Study	Assessment factor
chronic AEL	0.021 mg/kg bw day	Carcinogenicity Cu-HDO	300
sub-chronic AEL	0.034 mg/kg bw day	developmental toxicity rabbit Cu-HDO	300
sub-acute AEL	0.102 mg/kg bw day	developmental toxicity rabbit Cu-HDO	100

Acceptable exposure scenarios	
Professional users	The exposure scenarios for industrial application (Specialised professional use) by manufacturing of engineered wood products (Filling and Loading, etc.) are acceptable
Non-professional users	Not relevant (only industrial use intended)
Indirect exposure as a result of use	The risk from the following exposure scenarios is acceptable: o acute and chronic exposure of professionals by processing treated wood composites when wearing gloves o acute exposure of general public by processing treated wood composites without wearing gloves o acute and chronic exposure of adults and children inhaling evaporated product from treated wood composites indoors The risk from the following exposure scenarios is not acceptable: o chronic exposure of general public by processing treated wood composites without wearing gloves o acute oral ingestion by infant chewing treated wood composites

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 4: DT_{50} = 1.26 days at 25 °C Metabolite: Cyclohexanone oxime
	pH 7: stable at 50°C
	pH 9: stable at 50°C
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	80-90 % degradation after 72 h. Fragmentation into cyclohexanone with light > 290 nm[1]
Readily biodegradable (yes/no)	No; (ca. 60% degradation in 30 days in a BOD Test after 69 days of pre-adaptation of the inoculum) Inherent Biodegradability: 98% elimination after 28 days; 57% of this elimination was due to adsorption within the first 3 hours;
Biodegradation in seawater	Utilization in seawater not intended
Non-extractable residues	---
Distribution in water / sediment systems (active substance)	---
Distribution in water / sediment systems (metabolites)	---

[1]study with low reliability code

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	---
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): --- DT_{50lab} (20°C, aerobic): ---
	DT_{90lab} (20°C, aerobic): ---
	DT_{50lab} (10°C, aerobic): ---
	DT_{50lab} (20°C, anaerobic): ---
	Degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	DT_{50f}: ---
	DT_{90f}: ---
Anaerobic degradation	---
Soil photolysis	---
Non-extractable residues	---
Relevant metabolites – name and/or code, % of applied a.i. (range and maximum)	---
Soil accumulation and plateau concentration	---

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	loamy sand 1: K_a^F = 20.5 K_d^F = 27 Ka_{oc}^F = 805 Kd_{oc}^F= 1064 loamy sand 2: K_a^F = 66.3 K_d^F = 103.3 Ka_{oc}^F = 10518 Kd_{oc}^F= 15472 loamy sand 3: K_a^F = 233.8 K_d^F = 343.8 Ka_{oc}^F = 10606 Kd_{oc}^F= 16293 loamy sand 4: K_a^F = 38.1 K_d^F = 53.7 Ka_{oc}^F = 3739 Kd_{oc}^F= 5261 clay loam/clay: K_a^F = 79.8 K_d^F = 93.5 Ka_{oc}^F = 4360 Kd_{oc}^F= 5112
Soil column leaching	No HDO in the seepage water detected

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	---
Quantum yield of direct photolysis	---
Photo-oxidative degradation in air	DT_{50} = 3.735 hours k_{OH} (K-HDO) = 34.3610 x 10^{-12} cm³/(molecule x sec)
Volatilization	Volatilization potential is very low because of the low vapour pressure and Henry constant

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	---
Surface water (indicate location and type of study)	---
Ground water (indicate location and type of study)	---
Air (indicate location and type of study)	---

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
Leuciscus idus	96 h	Mortality	LC_{50} = 51.3 mg/L
Invertebrates			
Daphnia magna	48 h	Immobilisation	EC_{50}: > 30 mg/L
Daphnia magna	21 days	Reproduction and survival	NOEC = 0.47 mg/L
Algae			
Desmodesmus subspicatus	72 h	Biomass	E_bC_{50} = 15.6 mg/L
		Growth rate	E_rC_{50} > 30 mg/L
			NOEC = 3.75 mg/L
Activated sludge	30 min	Respiration inhibition	EC_{50}(30 min): 9 mg K-HDO / L EC_{20}(30 min): 1.44 mg K-HDO / L
Sediment-dwelling organisms			

Effects on earthworms or other soil non-target organisms

Acute toxicity to Eisenia fetida	Measured values: LC_0: ≥ 300 mg K-HDO / kg soil dry weight LC_{50}: > 300 mg K-HDO / kg soil dry weight NOEC: 30 mg K-HDO / kg soil dry weight Results converted to standard soil: LC_0: ≥ 102 mg K-HDO / kg soil dry weight LC_{50}: 102 mg K-HDO / kg soil dry weight NOEC: 10.2 mg K-HDO / kg soil dry weight
Acute toxicity to plants	---

Effects on soil micro-organisms

Nitrogen mineralization	Measured value: NOEC ≥ 30 mg KHDO / kg dry soil Converted to standard soil: NOEC ≥ 40.8 mg KHDO / kg dry soil (4.4% increase after 28 days)
Carbon mineralization	Measured value: NOEC ≥ 30 mg KHDO / kg dry soil Converted to standard soil NOEC ≥ 40.8 mg KHDO / kg dry soil (1.9% inhibition after 28 days)

Effects on terrestrial vertebrates

Acute toxicity to mammals	Section A6.1
Acute toxicity to birds	---
Dietary toxicity to birds	---
Reproductive toxicity to birds	---

Effects on honeybees

Acute oral toxicity	---
Acute contact toxicity	---

Effects on other beneficial arthropods

Acute oral toxicity	---
Acute contact toxicity	---
Acute toxicity to ……..	---

Bioconcentration

Bioconcentration factor (BCF)	0.134
Depration time (DT_{50}) (DT_{90})	---
Level of metabolites (%) in organisms accounting for > 10 % of residues	---

Appendix II: List of Intended Uses

K-HDO is intended to be used as wood preservative (product type 8) for the protection of wood composites against wood-destroying fungi (*basidiomycetes* as brown rot and white rot).

Since no insecticidal effect was shown, K-HDO treated wood composites are not applicable for use class 1 but only for use class 2 conditions meaning a situation in which wood or wood – based product is under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting. Main applications of K-HDO treated wood composites are within roof construction and outdoor under roof. Use within indoor living areas with the potential of direct contact is not foreseen by the applicant and should not be intended according to the evaluation in the Competent Authority Report.

The applicant intended to use K-HDO for application with particle boards, oriented strandboards, plywood and laminated veneer lumber. However, sufficient efficacy data were provided only for particle boards.

Application of K-HDO to wood composites is foreseen only within industrial fully automated systems (glue-line addition, i.e. blending of preservative and resin. The resin mixture is applied to the timber chips or veneers before the pressing of the boards. Alternatively, resin and preservative can be applied separately if interfering contact between preservative and resin has to be avoided). This allows strongly restricting worker and environmental exposure. The category of user is "industrial user".

Summary of intended uses

Object and/or situation	**Member State or Country**	**Product name**	**Organisms controlled**	**Formulation**		**Application**			**Applied amount per treatment**		**Remarks**
				Type	Conc. of a.s.	method kind	number min max	interval between applications	g a.s /m^3 min	max	
Particleboards and Oriented strandboard (OSB) [1]	EU	Xyligen 30 F	Wood destroying fungi (*basidio-mycetes*)	Liquid; ready to use	30 % (w/w)	Mixing with glue	1	-	1.8	2.6	Preser-vative treatment
Plywood [1] and Laminated Veneer Lumber (LVL)[1]	EU								1.5	2.6	

[1] The applicant intended to support efficacy with particle boards, OSB, plywood and LVL. However the efficacy data submitted were only sufficient for particle boards, not for OSB, plywood and LVL.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes data protection is claimed under Article 12.1(c) (i) or (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Section No	**Year**	**Title** **Source (where different from company) Company, Report No.** **GLP or GEP status (where relevant) Published or not**	**Data Protection Claimed** **Y/ N**	**Owner**
A 2.6	2004	"Product identity and Composition of (N-cyclohexyldiazeniumdioxy)-potassium"	Y	Dr. Wolman GmbH
A 2.8	2003	"Chemical 5 batch analysis of Xyligen 30 F"	Y	BASF
A 2.10.2.2	2005b	"Surface coatings of wood based panels"	Y	Dr. Wolman GmbH

Section No	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 3.1.1/01	2001	"Physico-chemical properties of (N-Cyclohexyl-diazeniumdioxy)-potassium"; BASF AG, Germany; BASF Report 01L00057; GLP; unpublished	Y	BASF
A 3.4/01	2001	"Characterisation of N-Cyclohexyl-diazeniumdioxy-potassium"; BASF AG, Germany; BASF Report 01L00234; GLP; unpublished	Y	BASF
A 3.4/02*	2004	"Spectroscopic characterisation of Xyligen Betriebsprobe"; BASF AG, Germany; Study No. 03L00371; GLP; unpublished	Y	BASF
A 3.4/03	2004	"Determination of the identity of Xyligen Betriebsprobe"; BASF AG, Germany; Study No. 04L00210; GLP; unpublished	Y	BASF
A 3.7	2004	"Solubility of K-HDO in organic solvents"	Y	Dr. Wolman GmbH
A 3.11	2001a	"Evaluation of safety characteristics according to 92/69/EEC, annex A9 – A17"; BASF AG, Germany; BASF Report SIK 01/0222; GLP; unpublished	Y	BASF

Section No	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 4.1/01	1992	Colorimetric determination of Xyligen potassium in Xyligen 30-F and in reaction preparations, BASF AG, Germany, BASF method M 92/9, unpublished, no GLP	Y	BASF
A 4.1/02	2003	"Determination of Chloride and Bromide by potentiometric Titration", BASF AG, GKA Analytik, test method 0021/05, unpublished, no GLP	Y	BASF
A 4.1/04	2005	"Determination of Sulphate in Xyligen 30F by ion-chromatography", BASF AG, GKA Kompetenzzentrum Analytik, method M05/0043/01, unpublished, no GLP	Y	BASF AG
A 4.1/05	2005	Validation of a Photometer method for the determination of K-HDO in water	Y	Dr. Wolman GmbH
A 4.1/06	2005	Concentration control analysis of N-Cyclohexyl-diazeniumdioxy-potassium in non Chlorinated Charcoal filtered tap water (Frankenthal, Germany, mixed with deionized water	Y	Dr. Wolman GmbH
A 4.2/01	2004a	Validation of a HPLC method for the determination of K-HDO in soil, Dr. Wolman GmbH, Germany, no GLP, unpublished	Y	Dr. Wolman GmbH

Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protec-tion Claimed (Yes/No)	Owner
A 5.3	2004	Bio-testing report - Effectiveness of K-HDO against wood destroying fungi, Biological Testing Laboratory, Dr. Wolman GmbH, Lab. Ref. B 1335-1983, no GLP, unpublished	Y	Dr. Wolman GmbH

Section No	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.1.1	1977	Report on the test of the acute oral toxicity of K-HDO in the rat, BASF AG AG Ludwigshafen, Germany, no GLP, unpublished	Y	BASF AG
A 6.1.2	1979	Report on the test of the acute dermal toxicity of K-HDO in the rat, BASF AG AG Ludwigshafen, Germany, no GLP, unpublished	Y	BASF AG
A 6.1.3.1	2001	Xyligen 30-F, acute inhalation toxicity study in Wistar rats, Report 13/0069/017001, BASF AG AG, GLP, unpublished	Y	BASF AG
A 6.1.3.2	1971a	Report on the test of the acute inhalation toxicity (inhalation risk) of Xyligen 30F in the rat, BASF AG AG, Ludwigshafen, Germany, no GLP, unpublished	Y	BASF AG
A 6.1.4	1971a	Report on the test of the primary irritant effect of Xyligen 30F on the skin and mucosa of rabbits, BASF AG Aktiengesellschaft, Ludwigshafen, Germany, no GLP, unpublished	Y	BASF AG
A 6.1.5	2004	Xyligen LP 15670: Testing of the skin sensitizating potential with the Local Lymph Node Assay, Laboratory Project ID Wol91, ARC Seibersdorf research GmbH, Austria, unpublished	Y	BASF AG
A 6.2.1	1993	Study on the Comparison of the adsorption and excretion of the potassium, copper and aluminium salt of 14-C-N Cyclohexyl-hydroxi-diazeniumoxide after oral, dermal and intravenous administration to Wistar rats, Report: 22B0638/896001, BASF AG AG, unpublished	Y	BASF AG
A 6.2.2	2001	14C-Cu-HDO Study of the Biokinetics in Rats, Report: 02B0881/006037, BASF AG AG, unpublished	Y	BASF AG
A 6.2.3	2002	The Metabolism of 14C-Cu-HDO in Rats, Report: 2002/1004467, BASF AG AG, unpublished	Y	BASF AG
A 6.2.4	2006	Study of penetration through human skin in vitro; BASF AG laboratory report number 52H0892/052243, unpublished	Y	BASF AG
A 6.3.1	1976	Study of the toxicity of Xyligen K powder in the 42-days feeding study, BASF AG Aktiengesellschaft, Ludwigshafen, Germany report, No. XXIII/280, no GLP, unpublished	Y	BASF AG
A 6.3.3	1978	Bericht über die Prüfung der subakuten Inhalationstoxizität von Reu-E 3403 (Xyligen-K) in Sprague-Dawley Ratten, BASF AG Aktiengesellschaft, Ludwigshafen, Germany, kein GLP, unpublished	Y	BASF AG
A 6.4.	1995	Subchronic oral toxicity study with Bis-(N-Cyclohexyldiazeniumdioxy)-copper in beagle dogs, Report: 31D0141/92060, BASF AG, unpublished	Y	BASF AG

Section No	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/ N	Owner
A 6.4.	1991	Report on the study of the oral toxicity of Bis-(N-cyclohexyl-diazeniumdioxy)-copper in rats Administration via the diet for 3 months; Report: 30C0679/89041, BASF AG, unpublished	Y	BASF AG
A 6.4.1	1978	3-Monate-Toxizität von Xyligen K, Charge 77/267 - kurz "Xyligen K" genannt - an Sprague-Dawley Ratten bei Verabreichung per Magensonde, Laboratorium für Pharmakologie und Toxikologie Prof. Dr. F. Leuschner, Hamburg, Germany, no GLP, unpublished	Y	BASF AG
A 6.5	1993	Report on the study of the chronic toxicity of Bis-(N-cyclohexyldiazeniumdioxy)-copper in rats, Report: 50C0679/89080, BASF AG AG, GLP, unpublished	Y	BASF AG
A 6.6.1	1989	Report on the study of N-Cyclohexyl-diazenium-dioxy-potassium-hydrat in the Ames Test (Standart plate test and preincubation test with Salmonella typhimurium), BASF AG Aktiengesellschaft, Ludwigshafen, Germany, GLP, unpublished	Y	BASF AG
A 6.6.3.1	1992	Rat hepatocyte DNA repair assay [UDS] in vitro: 81MO679/894495, BASF AG AG, GLP, unpublished	Y	BASF AG
A 6.6.3.2	2005	Mutagenicity study of Xyligen LP 15671 in the mouse lymphoma forward mutation assay –in vitro- Laboratory of Pharmacology and Toxicology KG, Hamburg, Germany LPT No. 18342/04, unpublished	Y	Dr. Wolman GmbH
A 6.6.4	1982	Cytogenetic investigations in NMRI mice after single oral administration of Xyligen-K powder, Micronucleus test, BASF AG Aktiengesellschaft, Ludwigshafen, Project No. 26MO172/8215, Germany, no GLP, unpublished	Y	BASF AG
A 6.7	1996	Carcinogenicity study with Bis-N-cyclohexyl-diazeniumdioxy)-copper in Wistar rats Administration in the diet for 24 months: 70C0679/89113, BASF AG AG, GLP, unpublished	Y	BASF AG
A 6.8.1.1	1991	Study of the Prenatal Toxicity of BIS-(N-CYCLOHEXYL-DIAZENIUMDIOXY)-COPPER in rats after oral administration (gavage): 30R0679/89059, BASF AG AG, GLP, unpublished	Y	BASF AG
A 6.8.1.2	1994	Study of the Prenatal Toxicity of BIS-(N-CYCLOHEXYL-DIAZENIUMDIOXY)-COPPER in rabbits after oral administration (gavage)administration (gavage): 40R0141/92031, BASF AG AG, GLP, unpublished	Y	BASF AG
A 6.9	1992	Report to the study of the oral toxicity of N-Cyclohexyldiazeniumdioxy-potassium-hydrate in Wistar rats, administration via the diet for 4 weeks, BASF AG Aktiengesellschaft, Ludwigshafen, Germany unpublished	Y	BASF AG

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A 7.1.1.1.1	2004b	Hydrolysis of K-HDO as function of pH, Report: 01/2002, Dr. Wolman GmbH, no GLP, unpublished	Y	Dr Wolman GmbH
A 7.1.1.1.2	1991	Degradation of HDO in aqueous solutions exposed to UV radiation, Dr. Wolman GmbH, no GLP, unpublished	Y	Dr. Wolman GmbH
A 7.1.1.2.1	1996	Prüfung der biologischen Abbaubarkeit von K-HDO, techn. 30 %ig im Verdünnungs BSB-test nach 30 Tagen, Report No: 95/0179/04/2; BASF Aktiengesellschaft, Emissionsüberwachung und Ökologie, Ludwigshafen, Germany, no GLP, unpublished	Y	BASF
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A 7.1.2.1.1	1980	Hydroxydiazeniumoxide (HDO) potassium salt – determination of the biological degradability in a long-term test, J-No. 63529, Analytical Laboratory, BASF Aktiengesellschaft, Ludwigshafen, Germany, no GLP, unpublished	Y	BASF
A 7.1.3/03	2006	Adsorption/desorption study with K-HDO according to OECD 106, Biochem. agrar, Report no 05 10 35 2029, BioChem agrar, BASF Aktiengesellschaft, Ludwigshafen, Germany, GLP, unpublished	Y	BASF
A 7.2.1	year unknown	Examinations concerning the degradation of HDO in soil, Dr. Wolman GmbH, Sinzheim, Germany, no GLP, unpublished	Y	Dr. Wolman GmbH
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A 7.2.3.2/02	1992	Mobility of active ingredients from Wolmanit CX pressure treated wood in soil – lysimeter test, Report No: 314; Dr. Wolman GmbH; no GLP, unpublished	Y	Dr. Wolman GmbH
A 7.4.1.1	1980	Report on the test of the acute toxicity of Xyligen 30F in fish (golden orfe - Leuciscus idus L.) BASF AG, Ludwigshafen, Germany, no GLP, unpublished	Y	BASF
A 7.4.1.2/01	2002	Xyligen K 30 F – Determination of the acute effect on the swimming ability of the water flea Daphnia magna Straus, Report 01/0069/50/2, Experimental Toxicology and Ecology, BASF AG, Ludwigshafen, Germany, GLP, unpublished	Y	BASF
A 7.4.1.2/02	1993a	Test Protokoll für den akuten 24 h/48 h Daphnientest nach DIN 38412, Teil 11, Umweltbundesamt (UBA), Institut für Wasser-, Boden- und Lufthygiene (BGA), Berlin, Germany, no GLP, unpublished	Y	BASF
A 7.4.1.3	2002	N-cyclohexyl-diazenium-dioxy-potassium - Determination of the inhibitory effect on the cell multiplication of unicellular green algae, Report 01/0069/60/1, BASF AG, GLP, unpublished	Y	BASF
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A 7.4.1.4/02	1993b	Testprotokoll für den Zellvermehrungshemmtest mit Pseudomonas putida nach DIN 38412, Teil 8, (1993) Umweltbundesamt (UBA), Institut für Wasser-, Boden- und Lufthygiene (BGA), Berlin, Germany, unpublished	Y	BASF
A 7.4.1.4/03	1993 c	Testprotokoll für den Leuchtbakterientest nach DIN 38412, Teil 34, Umweltbundesamt (UBA), Institut für Wasser-, Boden- und Lufthygiene (BGA), Berlin, Germany, no GLP, unpublished	Y	BASF
A 7.4.3.4	2002	Influence of Xyligen K 30 F on Survival and Reproduction of Daphnia magna in a semi static test over 21 days. Report 13601221, IBACON, GLP, unpublished	Y	BASF
A 7.5.1.1/01	2004a	Effects of Cu-HDO on the activity of soil microflora (Nitrogen transformation test), Report 04 10 35 2001 N, Biochem agrar, GLP, unpublished	Y	Dr. Wolman GmbH

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A 7.5.1.1/02	2004b	Effects of Cu-HDO on the activity of soil microflora (Carbon transformation test), Report 04 10 35 2001 C, Biochem agrar, GLP, unpublished	Y	Dr. Wolman GmbH
A 7.5.1.1/03	2005a	Effects of Xyligen LP 15684 on the activity of soil microflora. (Carbon transformation test), BioChem agrar, Labor für biologische und chemische Analytik GmbH, Report No.: 04 10 35 2026 C, GLP, unpublished	Y	Dr. Wolman GmbH
A 7.5.1.1/04	2005b	Effects of Xyligen LP 15684 on the activity of soil microflora (Nitrogen Transformation Test), BioChem agrar, Labor für biologische und chemische Analytik, report No.: 04 10 35 2026 N, GLP, unpublished	Y	Dr. Wolman GmbH
A 7.5.1.2	1992	Effect of Cu-HDO on the mortality of the earthworm Eisenia foetida: Report P92-E106, BASF AG, GLP, unpublished	Y	BASF
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A 7.5.1.3	2003	Wolmanit CX-LP 15172-Determination of the effect on the emergence, growth, and the observation of morphological changes of rice (Oryza sativa L.) Experimental Toxicology and Ecology, BASF AG, Report 03/0050/65/1, unpublished	Y	BASF

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B 3.1	2003a	Odour, physical state and pH – Xyligen 30 F -, Dr. Wolman GmbH, Project No. U 9584, no GLP, unpublished	Y	Dr. Wolman GmbH
B 3.2	2001b	Evaluation of safety characteristics according to 92/69/EEC, Annex A9 – A17, BASF AG, Report No.: SIK-Nr. 01/0222, March 16, 2001, GLP, unpublished	Y	BASF AG
B 3.6	2003b	Density – Xyligen 30 F –, Dr. Wolman GmbH, Project No. U 9585, no GLP, unpublished	Y	Dr. Wolman GmbH
B 3.7/01	2003c	Accelerated Storage test by heating CIPAC-MT 46 Xyligen 30 F, Dr. Wolman GmbH, Project No. U 9503, no GLP, unpublished	Y	Dr. Wolman GmbH
B 3.7/02	2004c	Low temperature stability according to CIPAC MT 39 – Xyligen 30 F-, Dr. Wolman GmbH, Project No. U 9583, no GLP, unpublished	Y	Dr. Wolman GmbH
B 3.7/03	2003d	Stability -Xyligen 30 F-, Dr. Wolman GmbH, Project No. U 9265, no GLP, unpublished	Y	Dr. Wolman GmbH
B 3.8	2004	Schaumverhalten von Xyligen K 30 F, Dr. Wolman GmbH, Sept. 2004, no GLP, unpublished,	Y	Dr. Wolman GmbH
B 3.10	2003	Determination of the surface tension of Xyligen 30 F according to EC Council Directive 92/69/EEC, A.5, Biochem, Labor für biologische und chemische Analytik GmbH, Study No. 04 50 40 800, GLP, unpublished,	Y	BASF AG
B 3.11	2004d	Viscosity – Xyligen 30 F -, Dr. Wolman GmbH, Project No. U 9586, no GLP, unpublished	Y	Dr. Wolman GmbH

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B 5.1.2	2002	Technical leaflet Xyligen 30 F	Y	Dr. Wolman GmbH
5.10.2/01	1987	Experimenteller Nachweis über die Wirksamkeitsdauer des Holzschutzmittels “Xyligen 25 F” in 10 Jahre alten Holzspanplatten der Type V 100 G, BAM Gutachten 5.1/4580-A, no GLP, unpublished	Y	Dr. Wolman GmbH
5.10.2/02	1972	Prüfung der fungiziden Wirksamkeit des Holzschutzmittels Xyligen 25 F (EH 4115 F) in Spanplatten mit Laubholzanteil, BAM Prüfungszeugnis 5.1/1971, no GLP, unpublished	Y	Dr. Wolman GmbH
5.10.2/03	1999	Bestimmung der Beständigkeit von Wisa-wire Baufurniersperrholzplatten gegen holzzerstörende Basidiomyceten nach ENV 12038; 7/1996, Dr. Wolman GmbH, Report No. N2707990, Laboratory of Mycology, no GLP, unpublished	Y	Dr. Wolman GmbH
5.10.2/04	2004	Statement on the Quality Management of Dr. Wolman GmbH	Y	Dr. Wolman GmbH

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B 6.1.1.	1971b	Test of the acute oral toxicity of Xyligen 30 F in the rat, BASF AG Medizinisch-Biologische Forschungslaboratorien, Test No. XX/195, May 12, 1971, no GLP, unpublished	Y	BASF AG
B 6.1.2	1971b	Report on the test of the acute dermal toxicity of Xyligen 30F in the rat, BASF AG, experiment No. XX/195, May 12, 1971, no GLP, unpublished	Y	BASF AG
B 6.6	2005a	Human exposure during production and application of Xyligen 30 F, Laboratory Project ID: 2811/2005, no GLP, unpublished	Y	Dr. Wolman GmbH
B 7.1	2006	Environmental exposure during production and application of Xyligen 30 F	Y	Dr. Wolman GmbH

Appendix IV - List of standard terms and abbreviations and List of abbreviations of organisation and publications

ADI	acceptable daily intake
ADME	administration, distribution, metabolism and excretion
AF	assessment factor
AI:	GIFAP abbreviation for active ingredient
ai	active ingredient
a.i.	active ingredient
ALT	alanine aminotransferase
AOEL	acceptable operator exposure level
appr.	approximate
approx	approximate
ARfD	acute reference dose
a.s.	active substance
AST	aspartate aminotransferase
AUC	area under curve
BCF	bioconcentration factor
BOD	biological oxygen demand
BPD	Biocidal Products Directive
bw	body weight
b.w.	body weight
BWC	body weight change
°C	degree celsius (centigrade)
CAS No.:	Chemical Abstracts Registry Number
CEC	cation exchange capacity
CHO	Chinese hamster ovary
CL	confidence limit
cm	centimetre
Cmax	maximal plasma concentration
CMC	carboxymethyl cellulose
COD	chemical oxygen demand
d	day
DAT	days after treatment
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid

DOC	dissolved organic carbon
DT_{50}	period required for 50 % dissipation
DT_{90}	period required for 90 % dissipation
EC_{50}	median lethal concentration
EINECS:	European inventory of existing commercial chemical substances
ELINCS:	European list of notified chemical substances
EN	European norm
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FID	flame ionization detector
FOB	functional observation battery
g	gram
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography – mass spectrometry
GLP	good laboratory practice
GPMT	Guinea Pig Maximisation Test
gw	ground water
h	hour
ha	hectare
HCl	hydrochloric acid
HPa	hectopascal
HPLC	high pressure liquid chromatography
HPRT	Hypoxanthine Guanine Phosphoribosyl Transferase
I_{50}	50% inhibition
IC_{50}	median immobilization concentration
ip	intraperitoneal
IR	infrared
iv	intravenous
k	kilo
Ka	acid dissociation constant
Kb	base dissociation constant

K_d	constant of adsorption
kg	kilogram
K-HDO	(N-cyclohexyldiazeniumdioxy)-potassium
K_{oc}	constant of adsorption related to organic carbon
K_{ow}	octanol-water partition coefficient
kPa	kilopascal
L	litre
l	litre
LD_{50}	median lethal dose
LC_{50}	median lethal concentration
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
Log	logarithm
log	logarithm to the base 10
m	metre
M	molar
MA	motor activity
MBq	Mega Becquerel
MCA	3-methylcholanthrene
mCi	Milli Curie
µg	microgram
µm	micrometre
mg	milligram
ng	nanogram
MHEC	methyl-hydroxyethylcellulose gel P 300
MIC	minimum inhibitory concentration
min	minute
mL	millilitre
ml	millilitre
mm	millimetre
MMAD	mass median aerodynamic diameter
MOE	margin of exposure
mol	mole
MOS	margin of safety
MT	Maximization Test
MWC	maximum water holding capacity

n.a.	not applicable
nd	not detected
Na-CMC	aqueous sodium carboxymethylcellulose
NCE’s	normo chromo erythrocytes
nd	not determined
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Cooperation and Development
Pa	pascal
PAI:	Pure active ingredient
p.c.	post coitum
PCE	Plasma cholinesterase
PCE's	polychromatic erythrocytes
PEC	predicted environmental concentration
pH	pH-value
p.i.	post insemination
pKa	negative logarithm to the base 10 of the acid dissociation constant
pKb	negative logarithm to the base 10 of the base dissociation constant
PNEC	predicted no effect concentratio
Pow	partition octanol water
p.p.	post partum
PPE	personal protective equipment
ppm	parts per million
PT	product type
QAU	quality assurance unit
(Q)SAR	quantitative structure – activity relationship
s	second
SD	standard deviation
sp	species

STP	sewage treatment plant
sw	surface water
t	tonne
TAR	total applied radioactivity
TC:	FAO abbreviation for a technical material
TER	toxicity exposure ratio
TGAI	technical grade active ingredient
TGD	technical guidance document
TIFF	tag image file format
TM	Technical Meeting (Biocides)
TNsG	technical notes for guidance
UDS	unscheduled DNA synthesis
UV	ultraviolet
vis	visible
wk	week
wt	weight
w/w	weight per weight
w/v	weight per volume
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
%	per cent

Note: The technical terms “active ingredient” and “active substance” are equivalent