K-HDO

(Cyclohexylhydroxydiazene 1-oxide, potassium salt)

Biocide for Use as Wood Preservative

Dossier According to Directive 98/8/EC

Document III-A

Data on the Active Substance

Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Name: Dr. Wolman GmbH (BASF Group)
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Germany
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Fax number: (49) 7221-800210
E-mail address: [redacted]@wolman.de, [redacted]@wolman.de

1.2 Manufacturer of Active Substance (if different)

Name: BASF Aktiengesellschaft
Address: Carl-Bosch-Straße 38
67056 Ludwigshafen
Germany
Telephone: (49) 621-60-0
Fax number: —
E-mail address: —
Location of manufacturing plant: 67056 Ludwigshafen, Germany

1.3 Manufacturer of Product(s) (if different)

1) Product 1 (Wolmanit CX)

Name: Dr. Wolman GmbH (BASF Group)
Address: Dr. Wolman-Str.31-33
76547 Sinzheim
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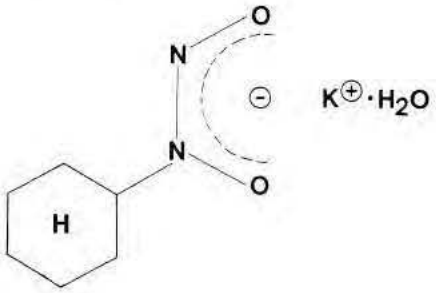
Section A2 Identity of Active Substance

Subsection (Annex Point)			**Official use only**
2.1	**Common name (IIA2.1)**	(N-cyclohexyldiazenium-dioxy)-potassium (the common name used is K-HDO)	X
2.2	**Chemical name (IIA2.2)**	(N-cyclohexyldiazenium-dioxy)-potassium (in the IUCLID-file and in the letter of acceptance used name)	X
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	K-HDO, Xyligen-K, K-NCH	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	66603-10-9	X
	Isomer 1		
	Isomer n		
2.4.2	**EC-No**	248-617-6	X
	Isomer 1		
	Isomer n		
2.4.3	**Other**		
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$C_6H_{13}N_2O_3K$	X
2.5.2	**Structural formula**		X
2.5.3	**Molecular mass**	200.28 g/mol	X
2.6	**Method of manufacture of the active substance (IIA2.1)**	**Information of this part is presented in the confidential appendix of Doc III A K-HDO**	

		g/kg	g/l	% w/w	% v/v	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**			30		X

Section A2 Identity of Active Substance

2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	see separate standard format	X
2.8.1	**Isomeric composition**		
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**		X

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	Nov 2005
Materials and methods	Agree with the applicant's version
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	acceptable

Remarks

2.1 Common Name, 2.2 Chemical name, 2.4 CAS No and EC numbers:

There are two different resonance structures existing for the active substance: a diazeniumdiolate form and a nitrosohydroxylamine form. Each form has its own CAS-No.:

- Cyclohexylhydroxydiazene 1-oxide, potassium salt
  CAS-No. 66603-10-9, EC-No. not attributed
- N-hydroxy-N-nitroso-Cyclohexanamine, potassium salt
  CAS-No. 27697-50-3, EC-No. 248-617-6
  (Name listed in ESIS: N-cyclohexyl-N-nitrosohydroxylamine, potassium salt)

On the basis of x-ray crystallography [redacted] (2002) suggest that the diazeniumdiolate form is predominating. This is the reason why the applicant indicates the CAS-No. 66603-10-9. The corresponding chemical name is Cyclohexylhydroxydiazene 1-oxide, potassium salt. The CAS-No. refers to the anhydrous form of the substance.

2.5.1 Molecular formula, 2.5.2 Structural formula, 2.5.3 Molecular mass:

The indicated molecular and structural formulas include one molecule of water of crystallisation. The molecular mass of the monohydrate is 200.28 g·mol^{-1}, without water of crystallisation the molecular mass equals to 182.269 g mol^{-1}.

2.7 Range of concentration:

The active substance as manufactured is K-HDO as aqueous solution; the concentration of K-HDO ranges from 30 to 31% (w/w). Abstracting the water content, K-HDO has a minimum purity of 97.7 %w/w.

2.8 Identity of impurities and additives, as appropriate (IIA2.8)
see Annex point II A2.8

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9) The precursors of the active substance are commercially available chemical substances. For more information, see "Doc. III-A – Appendix 2 – Confidential data and information"

COMMENTS FROM ...
Date
Results and discussion
Conclusion
Reliability
Acceptability
Remarks

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection						**Official use only**
2.8.1.1	**Common name**					
2.8.1.2	**Function**	Information of this part is presented in the confidential appendix of Doc III A K-HDO				X
2.8.2	**IUPAC name**					
2.8.3	**CAS-No**					
2.8.4	**EC-No**					
2.8.5	**Other** CIPAC					
2.8.6	**Molecular formula**					
2.8.7	**Structural formula**					
2.8.8	**Molecular mass**					
2.8.9	**Concentration of the impurity or additive**	g/kg	g/l	% w/w	% v/v	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Nov 2005
Materials and methods	–
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	acceptable
Remarks	This applies to all additives and impurities (10 listed). In reference A 2.8 [redacted], "Chemical 5 Batch Analysis of Xyligen 30 F", March – June 2003, BASF AG, Ludwigshafen, impurities are identified and quantified (Document IV level). Moreover, analytical methods of their detection are listed.

	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection

Official use only

2.10.1 Human exposure towards active substance

2.10.1.1 Production

		Official use only
i) Description of process	Information of this part is presented in Appendix 2, Doc III A, "confidential data and information active substance"	
ii) Workplace description	The plant is located together with the container filling in a closed building. The filling of the street-tank-train occurs on a roofed outdoor filling point.	
iii) Inhalation exposure	Work place concentration measurements are continuously performed. Limit values are always maintained.	X
iv) Dermal exposure	There is no skin contact with the used substances. In case a skin contact is imaginable, the operating instruction stipulates personal protective equipment (i.e. rubber gloves).	X

2.10.1.2 Intended use(s) Protection of wood composites against attack by wood-destroying fungi.

1. Professional Users

i) Description of application process

Use Patterns

Xyligen 30 F is applied to the timber chips or veneers during manufacturing of the boards in industrial scale process units. Two methods can be used for this purpose.

The most common method in Europe is the glue-line addition, ie. blending of preservative and resin. The resin mixture is then applied to the chips before the pressing of the boards. Alternatively, separate nozzles can be used if contact between preservative and resin has to be avoided. In both cases, the application of the preservative is incorporated in the manufacturing process and does not require any additional equipment.

Preparation of the preservative/resin mixture

Xyligen 30 F is delivered in bulk containers or in tank truck. The bulk containers are stored in designated storage areas within the production hall. If delivered by tank trucks, the preservative is transferred via closed transfer lines to storage tanks designed for this purpose.

Mixing of preservative and resin is fully automatic and controlled by gravimetrical or volumetrical methods and computer systems. Transfer lines are attached to the storage tanks for the resin, preservative and additional chemicals eg. hardener, water etc.

Treatment Process

The preservative is applied to the boards at the stage of gluing and pressing. The wood material is processed to the requirements of the individual types of engineered wood products. This can include drying, cutting etc.

Particleboards and Oriented strandboard (OSB)

Chips for eg. particle board or OSB are transported to rotary barrel mixers by conveyors. The mixers are closed and are fed with the resin/preservative mixture, which is sprayed on the wooden chips inside the mixers. Alternatively, separate nozzles for resin, preservative, hardener etc. may be available inside the mixer. In this case blending of resin and preservative is not necessary.

Plywood and Laminated Veneer Lumber (LVL)

The glue for plywood is applied between individual veneers by rolls before pressing. All engineered wooden products will be compressed at this stage. Pressure, temperature and compression time are variable depending on process, type of engineered wood product etc. Typically, temperatures of 100 +/-50 °C may be expected.

In general, the preservative treatment is part of a fully automatic, non-stop process and needs little supervision by human personnel.

ii) Workplace description

Filling/loading:

Xyligen 30 F is unloaded from the delivering tank truck into a holding tank of the processing company via a pipeline or delivered in intermediate bulk container.

Production/cleaning

In the production hall the Xyligen 30 F will be sub-mixed fully automatically into the paste and then pressed to chipboards. Cleaning of the Xyligen 30 F tanks or the pipelines does not occur.

The production of the Xyligen 30 F treated wood composites is fully automatically without direct involvement of personnel.

iii) Inhalation exposure

Inhalation exposure = 0,00137 mg K-HDO per kg bw per day x

These calculations present worst-case scenarios because in praxis no personnel is involved in the production process and hence the inhalation of Xyligen 30 F is negligible

iv) Dermal exposure

Normal risk: x

Xyligen 30 F is unloaded from the delivering tank truck into a holding tank of the processing company. If required, the Xyligen 30 F will be sub-mixed fully automatically into the paste and then pressed to chipboards. Cleaning of the Xyligen 30 F tanks or the pipelines does not occur. The direct contact of workers with treated panels is excluded due to the automatic production process and the automatic packaging system.

Worst case:

- Filling and loading (mixing):

  Dermal absorption per day and kg for loading and filling = 8,28 ng/kg day.
- indirect exposure:

  Assuming gloves (12 % penetration accepted according to TGD) as protective equipment dermal absorption amounts to:

  Dermal absorption per day and kg for contact = 54 ng / kg/day

Overall dermal absorption:

54 ng/kg/day d + 8,28 ng/kg day = 62,28 ng/kg day K-HDO

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

	Overall exposure (Dermal absorption + Inhalative exposure): 1,43 µg/kg/day **(TER) for primary exposure from industrial use** TER = 4196	
2. Non-professional Users including the general public	**Primary exposure** Primary exposure (from application) of non-professionals is not possible because Xyligen 30 F is only applied by professionals in industry. **Secondary exposure (post-application):** **1. Adult: sanding treated wood posts –inhalation route** Systemic dose (60 kg person): 0,36 µg/kg bw K-HDO TER = 16666 **2. Infant acute: chewing wood off-cut – ingestion route** Systemic dose (10 kg person): 432 µg/kg bw K-HDO TER = 314,8	X
(i) via inhalational contact	**3. Chronic: inhalation of volatilised residues indoors-inhalation route** Adult: BW = 60 kg = 0,025 µg/kg bw Child: BW = 15 kg = 0,0219 µg/kg bw; TER = 273973	X
(ii) via skin contact		X
(iii) via drinking water	Not applicable	
(iv) via food	Not applicable	
(v) indirect via environment	Not applicable	
2.10.2 Environmental exposure towards active substance		X
2.10.2.1 Production		
(i) Releases into water	The production of the active substance (N-Cyclohexyldiazeniumdioxy)-potassium / Xyligen 30 F is always carried out in closed systems with the safety measures customary nowadays in the chemical industry. Thus, under normal conditions, there is no possibility of emission of K-HDO to water. The receiving sewage water (e.g. cooling water, rain water) not containing K-HDO is supplied to the waste water system of the plant Ludwigshafen and will be cleaned in the sewage plant of BASF Ludwigshafen.	X
(ii) Releases into air	The emissions of the plant will be transmitted by an accumulative gas pipe to a thermal afterburning unit without regulated air supply. Extrusion of the air out-of-doors occurs by filling of the tank trucks.	X
(iii) Waste disposal	The waste of the plant will be burned in the plant-owned residue combustor.	
2.10.2.2 Intended use(s)	K-HDO is used as 30 % aqueous solution (Xyligen 30 F) for the preservation of wood composites.	X

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

The production is always carried out in closed systems with the safety measures customary nowadays in the chemical industry. Thus, under normal conditions, there is no possibility of release of K-HDO to the environment.

Wood-based panels equipped with fungicides, such as plywood or particleboards, are mainly used in hazard class 1 and 2 situations (inside, outside under roof). Outside use of wood-based panels does normally not occur without protection against direct weathering by additional coatings (see reference A 2.10.2.2). These coatings form a barrier and prevent any leaching. The coating consists of a phenolic film. The edges are protected by Acrylic-based paint.

A release of K-HDO into the environment by washing out can be excluded.

Because of the very low vapour pressure, a release into the environment by evaporation can be disregarded.

The product can only get into the environment in the case of an accident

Affected compartment(s):		x
water	Not affected	
sediment	Not affected	
air	Not affected	
soil	Not affected	
Predicted concentration in the affected compartment(s)		
water		
sediment		
air		
soil		

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date February 2006

Materials and methods –

Conclusion Agree with the applicant's version

Reliability 2

Acceptability acceptable with revisions for data calculation (see remarks)

Remarks

2.10.1 Human exposure towards active substance

2.10.1.1 Production

iii) Inhalation exposure

Since Xyligen 30 F is produced in a continuous, entirely closed system, inhalation of vaporised K-HDO could only occur during container/tank-train filling and maintenance of equipment. This exposure is infrequent and not a consequence of normal work practice. In addition the concentration in air is limited by the vapour pressure and won't exceed the concentration during application of the product. On these grounds, inhalation exposure during application is considered to be negligible.

iv) Dermal exposure

Incidental contact is just possible during container/tank-train filling and maintenance of equipment. The exposure concerned would be exposure of a part of the hands. This dermal exposure is infrequent and not a consequence of normal work practice; it occurs only occasionally and it may involve different persons for each shift. Workers are specifically trained and expected to wear adequate personal protective equipment according to the risk classification and the safety recommendations given in the safety data sheet. Therefore dermal exposure can be considered disregardable in comparison to dermal exposure during application.

2.10.1.2 Intended use(s)

1. Professional

iii) Inhalation exposure

The inhalation exposure given by the applicant is based on the saturated air concentration of K-HDO at 293 K. We think inhalation exposure is at maximum during compression of already impregnated wood flakes. Hence, the calculation should consider the highest temperature used i.e. 423 K. In addition, the used molecular weight of K-HDO was incorrect.

Therefore the risk of inhalation exposure caused by the use of Xyligen 30 F was recalculated from the following equation:

$$W = (P*V*M) / (R*T)$$

where W is the amount of substance in 1 m^3 air (g)
P is the vapour pressure (<0.0001 Pa)

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

V is the volume of air (1 m^3)
M is the molecular weight (182 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature during compression (423 K; temperature during compression)

Using the values listed above, the saturation concentration is calculated to be <5.2 µg/m^3 (realistic worst case). Taking into account that the production takes place in a ventilated work area, the concentration is reduced to 1 % of the saturation concentration, i.e. <0.052 µg/m^3 (normal use). Taking also into account an inhalation rate of 1.25 m^3/h, a work day of 10 hours and an adult of 60 kg, this would lead to an inhalation exposure of <1.1 µg K-HDO/kg bw/day (realistic worst case) and < 0.011 µg K-HDO/kg bw/day (normal use).

iv) dermal exposure

Filling and Loading:

The dermal exposure given by the applicant is based on TNsG on human exposure, part2, model 7 considering 4 % dermal up-take and a maximum contact time of 5 minutes per day. According to the evaluation of the dermal up-take study 4% dermal absorption should be used. Moreover maximum contact of 1 minute is assumed to be underestimated.

Therefore, dermal exposure during filling and loading was recalculated as follows:

Assuming no protecting gloves and a dermal skin absorption from 100 % the following exposure can be calculated:

Dermal exposure (conservative approach) = maximum contact time x exposure value x content K-HDO
= 5 min x 1.38 mg concentrate x 0.3
= 2.07 mg

For loading and filling process the daily exposure for a worker with an averaged body weight of 60 kg amounts to

Dermal exposure (conservative approach) per kg bw = 34.5 µg/kg bw

Assuming gloves (12% penetration) and a dermal absorption of 4% the dermal absorption amounts to

Dermal exposure (normal use) per kg = 34.5 µg/kg bw x 0.04 x 0.12 = 0.17 µg/kg bw

Indirect exposure:

Dermal exposure of workers handling treated panels was estimated on the basis of an US exposure model for children playing on playground equipment. This assessment implies a wipe test study of Cu-HDO from vacuum pressure treated wood after 20 days weathering.

In our opinion this assessment is not adequate, particularly since K-HDO is not applied by vacuum pressure but by glue-line addition and no weathering occurs. Therefore, as a worst-case the exposure of a worker handling treated panels is estimated on the basis of the secondary exposure assessment of Xyligen 30 F treated wood (dermal uptake during processing of treated wood, see below).

Toxicity/Exposure Ratios:
TERs should be discussed in Document II-C.

2. Non-professional Users including the general public
Secondary exposure:
(i) via inhalational contact and (ii) via skin contact
Insufficient scenarios are provided by the applicant.
In our opinion secondary exposure assessment should also consider chronic inhalation during sanding/processing as well as acute and chronic dermal uptake during processing of treated wood.

In addition, some of the used values were incorrect, e.g. the used molecular weight of K-HDO and the dermal absorption. Hence, secondary exposure was reevaluated.

Overview of secondary exposure*:*

Summary of secondary exposure estimates – Tier 1

Exposure scenario	**Inhalation uptake**	**Dermal uptake**	**Oral uptake**
Acute exposure during processing of wood	0.000395 mg a.s./kg bw	0 36 mg a.s./kg bw	-
Acute oral ingestion by infant by chewing wood	-	-	4.16 mg a.s./kg bw
Chronic exposure during processing of wood	0.0023 mg a.s./kg bw/d	0 36 mg a.s./kg bw/d	-
Chronic inhalation of volatile residues indoors by adult	<0.0028 mg a.s. /kg bw/d	-	-
Chronic inhalation of volatile residues indoors by infant	<0.0029 mg a.s. /kg bw/d	-	-

Summary of secondary exposure estimates – Tier 2

Exposure scenario	**Inhalation uptake**	**Dermal uptake**	**Oral uptake**
Acute exposure during processing of wood	not calculated, assume same value as in Tier 1	0.0017 mg a.s./kg bw	-
Acute oral ingestion by infant by chewing wood	-	-	0.416 mg a.s./kg bw
Chronic exposure during processing of wood	not calculated, assume same value as in Tier 1	0.0017 mg a.s./kg bw/d	-
Chronic inhalation of volatile residues indoors by adult	$<2.8*10^{-5}$ mg a.s. /kg bw/d	-	-
Chronic inhalation of volatile residues indoors by infant	$<2.9*10^{-5}$ mg a.s. /kg bw/d	-	-

It is difficult to summarise the amended secondary exposure in just a few lines. Please refer to the Dossier Document II-B for the full overview.

2.10.2 Environmental exposure towards active substance

For detailed information see reference B 7.1 [redacted], 2006)

2.10.2.1 Production

(i) Releases into water

The applicant stated that excess of reaction fluids will be recirculated.

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

(ii) Releases into air
Potential environmental exposure via filling of the tank trucks is considered negligible.

2.10.2.2 Intended use(s)
No efficacy claim against insects has been proven by the applicant. Therefore use class 1 is not relevant. Only use class 2 is supported based on the fungicidal efficacy data. Generally wood composites are no target for European insects, except for termites.

Affected compartment(s):
Manufacturing process of the biocidal product:
The production is carried out in an entirely closed systems, thus, under normal conditions, there is no possibility of release of K-HDO to the environment.

Industrial application of the biocidal product:
Exposure during to all environmental compartments is considered to be insignificant because of the use pattern of the biocidal product during application.

Treated wood in service:
According to the Emission Scenario Document for Wood Preservative (OECD, 2003) potential emissions from treated wood (use class 2) to the environment can be considered negligible.

COMMENTS FROM ...

Date

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.1 Melting point, boiling point, relative density (IIA3.1)								X
3.1.1 Melting point	OECD Guide-line 102 "Melting Point/Melting Range	p.a. substance	**result:** The DSC diagram shows one reversible endothermal peak upon heating. The mean value of the extrapolated onset of this endothermal peak is at 163.1 C.		Y	1	A 3.1.1/01 [redacted] (2001) Physico-chemical properties of (N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X
3.1.2 Boiling point	OECD Guide-line 102 "Melting Point/Melting Range	p.a. substance	**result:** DSC measurements show, that at about 210 C the test item starts decomposition. Therefore, no boiling point is reported.		Y	1	A 3.1.1/01 [redacted] (2001) Physico-chemical properties of (N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.1.3 Bulk density/ relative density	OECD Guide-line 109 "Density of Liquids and Solids	p.a. substance	1.431 at 20 C		Y	1	A 3.1.1/01 [redacted] (2001) Physico-chemical properties of (N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X
3.2 Vapour pressure (IIA3.2)	Directive 92/69/EEC, A.4	p.a. substance	**temperature:** 50 C **result:** < 0.000001 hPa at 50 C		Y	1	A 3.1.1/01 [redacted] **(2001)** Physico-chemical properties of N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	Calculation	-	**calculated result:** The resulting Henry constant of the active substance is $H = 4.4 \cdot 10^{-11}$ kPa m3/mol.		Y	1	-	X
3.3 Appearance (IIA3.3)								
3.3.1 Physical state			liquid					X
3.3.2 Colour			yellowish					X
3.3.3 Odour			weak					X

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.4 **Absorption spectra (IIA3.4)**								X
UV/VIS and IR	Measurement of spectra	p.a. substance	The structure of K-HDO is confirmed by all spectra		Y	1	A 3.4/01 Dr. Schmidt (2001) Characterization of " N-Cyclohexyl-diazeniumdioxy-potassium BASF AG, Germany BASF Report 01L00234 unpublished	X
NMR	1-H-NMR-spectra	Xyligen, 30 %	The identity of the test item was approved by 1H-NMR		Y	1	A 3.4/03 Dr. Krack, (2004) Determination of the identitiy of Xyligen Betriebsprobe, Study No. 04L00210, BASF AG, unpublished	X
MS	MS-LS, ES- ionisation, positive and negative mode	Xyligen 30 F	The spectra showed signals expected for the structure of the test item		Y	1	A 3.4/02 Dr. Euler, 20. Jan 2004 Spectroscopic characterisation of Xyligen Betriebsprobe, BASF AG, Germany Study No. 03L00371, unpublished	X

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.5 **Solubility in water (IIA3.5)**	*including effects of pH (5-9)*							
	Directive 92/69/EEC, A.6	p.a substance	result: The water solubility of the test substance at 20 C amounts to 452 g/l temperature and pH: Due to the high solubility pH and temperature effects were not measured within the study.		Y	1	A 3.1.1/01 Dr. Büldt (2001) Physico-chemical properties of N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X
3.6 **Dissociation constant (-)**	OECD Guide-line 112	p.a. substance	The pKa value of K-HDO was determined by potentiometric titration, The measurement was performed with a test solution of 0.0005 mol/l. The pKa value amounts to 5.33 +/-0.02.		Y	1	A 3.1.1/01 Dr. Büldt (2001) Physico-chemical properties of N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.7 **Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)**			Statement: K-HDO is an ionic compound without lipophilic structure components. The solubility in ethylene glycol amounts to 54 g/100 g at 20 C. K-HDO is readily soluble in ethanol, methanol and dimethylformamide. The temperature effect of the solubility in organic solvents was not determined in a special study, because K-HDO is readily soluble in different organic solvents.	Determination of the solubility is not required, because K-HDO is used in aqueous systems only.	N	1	A 3.7 Statement	X
3.8 **Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)**			Statement: The stability in organic solvents was not determined, because K-HDO is used in water based systems only	Determination of the stability is not required, because K-HDO is used in aqueous systems only.		1	Statement	X

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.9 Partition coefficient n-octanol/water (IIA3.6)	*including effects of pH (5-9)* Shake flask method, 92/69/EEC, A8: determination of K-HDO in octanol and water phases with HPLC/UV after phase separation	p.a. substance	result: log Pow= -0,2 at 25 C temperature: 25 C pH: 7,2 pH of the test substance depends on the test concentration. Therefore, measurement was performed by a buffered pH-value of 7.2. According to the guideline, measurement is not required at different pH-values and temperatures.	K-HDO is readily soluble in water and organic solvents. Therefore no temperature dependence of the log Pow is expected.			A 3.1.1/01 Dr. Büldt (2001) Physico-chemical properties of N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	DSC measurements in agreement with OECD 102 with a hermetically sealed, high pressure crucible		DSC measurements show, that at about 210 C the test item starts decomposition.				A 3.1.1/01 Dr. Büldt (2001) Physico-chemical properties of N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.11 **Flammability, including auto-flammability and identity of combustion products (IIA3.8)**	Directive 92/69/EEC, A.16	p.a. substance	The relative self-ignition temperature is 250 C		Y	1	A 3.11 Dr. Löffler (2001) Evaluation of safety characteristics according to 92/69/EEC, annex A9-A17 BASF AG, Germany BASF Report SIK 01/0222 unpublished	X
3.12 **Flash-point (IIA3.9)**	Directive 92/69/EEC, A.10	p.a. substance	the test substance is considered highly flammable		Y	1	A 3.11 Dr. Löffler (2001) Evaluation of safety characteristics according to 92/69/EEC, annex A9-A17 BASF AG, Germany BASF Report SIK 01/0222 unpublished	X

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.13 Surface tension (IIA3.10)	OECD Guide-line 115, Ring method	p.a.- substance	result: 71.4 mN/m +/- 0.2 at 20 C temperature: at 20 C		Y	1	A 3.1.1/01 Dr. Büldt (2001) Physico-chemical properties of N-Cyclohexyl-diazeniumdioxy)-potassium BASF AG, Germany BASF Report 01L00057 unpublished	X
3.14 Viscosity (-)			result: temperature:	Only if additional data are required (see BPD, TNsG) K-HDO is a solid. Therefore, no viscosity was determined. The viscosity of the technical active ingredient (30 % K-HDO in water) is given in document III-B				

Section A3 **Physical and Chemical Properties of Active Substance**

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.15 Explosive properties (IIA3.11)	Directive 92/69/EEC, A.14	p.a.. substance	The test substance is not considered to present a danger of explosion in the sense of the directive		Y	1	A 3.11 Dr. Löffler (2001) Evaluation of safety characteristics according to 92/69/EEC, annex A9-A17 BASF AG, Germany BASF Report SIK 01/0222 unpublished	
3.16 Oxidizing properties (IIA3.12)	Directive 92/69/EEC, A.17	p.a. substance	The test substance is not considered as an oxidizing substance		Y	1	A 3.11 Dr. Löffler (2001) Evaluation of safety characteristics according to 92/69/EEC, annex A9-A17 BASF AG, Germany BASF Report SIK 01/0222 unpublished	X
3.17 Reactivity towards container material (IIA3.13)	K-HDO is not stored or transported as an isolated solid; therefore, this study is not required for the pure, active ingredient. The stability against container material was investigated with the technical material. Reference is made to document III B.							X

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Oct 2005
Materials and methods	*3.1, 3.2, 3.4, 3.5, 3.6, 3.9, 3.10, 3.13* **Purity/Specification:** All references refer to batch W-87; according to A 3 1 1/01 the purity is 90 8%; according to A 3 4/01 the purity is 91 1% and 100% when calculated as monohydrate (A 3 4/01) These specifications can be regarded as equal: When the present one mole water of crystallisation is taken into account in A 3 1 1/01 and A 3 4/01, the purity of the purified active substance is ≥ 99 7% **Reference**: We received two different documents with the identification number A3 1 1/01 This section is related to the one which dates from 03/2004 *3.1.1 Melting Point* **Method:** The employed method was DSC (differential scanning calorimetry) *3.1.3 Bulk density/relative density* **Method:** OECD 109 (1995), pycnometer method; RD = 1 431 ± 0,001 at 20 °C *3.2 Vapour pressure (IIA3.2)* **Results:** $p_{vp} < 10^{-6}$ hPa at 20°C and $< 10^{-6}$ hPa at 50°C **Reliability:** 2 *3.2.1 Henry's Law Constant* **Results:** The formula for calculation of Henry's Law Constant is $H = P_{VP} \cdot M/S$ with P_{VP} (vapour pressure at 25°C) = 10^{-7} kPa M (molar mass of KHDO monohydrate) = 200 28 g/mol S (water solubility) = 452000 g/m^3 *3.3 Appearance (IIA3.3)* **Results:** active substance (30% KHDO in water): clear amber coloured liquid, characteristic odour (references A3 4/03, B3 1) purified active substance (solid, purity ≥99 7%): white crystalline powder, homogenous by visual inspection (A 3 4/01) *3.4 Absorption spectra (IIA3.4)* **Reliability:** 2 **MS, reference:** The quoted reference, which is labelled as A 3 4/02 in this section, was sent to us with the number A 3 1 1/01 in Sept 2004 and must not be mixed up with A3 1 1/01 which we received in March 2004 **UVIVIS absorption spectra**: absorption maximum at 237 nm 3 5 *Solubility in water* **Method:** flask method **Results:** solubility at T=20°C ± 1°C = 452 g/l ± 1 g/l *3.7 Solubility in organic solvents, including the effect of temperature on solubility* **Results:** The test wasn't carried out, but as in statement A 3 7 the worst case scenario is presumed (readily soluble in organic solvents), the justification can be accepted

	3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products: The statement can be accepted, since there are no organic solvents used in the biocidal product *3.9 Partition coefficient n-octanol/water (IIA3.6)* **Results:** deviation from 92/69/EEC, A8: Instead of distilled or double distilled water a buffer solution (pH 7, Bernd-Kraft GmbH) was used **Remark:** K-HDO is readily soluble in water and ethylene glycole ***GLP (Y/N):*** Y; **reliability:** 2 *3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)* **Method:** also corresponding to OECD Guideline 113 **Results:** Breakdown products are only required where possible **Reliability:** 2 *3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)* **Method:** Flammability : Directive 92/69/EEC, A 10 Self-Ignition: Directive 92/69/EEC, A 16 **Purity/Specification:** Batch number W-87, purity and moisture content not specified in this study (A 3 11) **Results:** 92/69/EEC, A 10: According to the burning rate test, the substance is considered to be highly flammable (burning time 21s) Combustion products were not identified 92/69/EEC, A 16: The relative self ignition Temperature is 250°C There is no self ignition at temperatures up to the melting point (163 1°C) *3.12 Flash-point (IIA3.9)* **error in numeration:** the original content of this subsection relates to 3 11 **Method:** 92/69/EEC, A 9 **Results:** This test wasn't conducted, because the purified active substance is solid and flash points are only defined for liquids Furthermore, the active substance as manufactured (30% KHDO in aqueous solution) does not possess any flash point because of the high water content *3.13 Surface tension (IIA3.10)* **Results:** The test item is not surface-active concentration of test solution: 1 g/L) *3.16 Oxidizing properties (IIA3.12)* **Results:** In the train test, the maximum burning rate of test mixtures is 3,4 mm/s (80% w/w of test substance, 20% w/w of cellulose) compared to 5mm/s of the test reference (bariumnitrate/cellulose mixture) *3.17 Reactivity towards container material* see Document IIIB, Section B 3, subsection 3 7
Conclusion	agree with applicant's version with the amendments above
Reliability	see single subsections
Acceptability	acceptable
Remarks	see materials and methods

Formatiert: Schriftart: Nicht Kursiv, Hervorheben

Formatiert: Schriftart: Nicht Kursiv, Schriftart für komplexe Schriftzeichen: Fett, Hervorheben

	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure active substance**

Official use only

1 REFERENCE

1.1	**Reference**	A 4.1 [redacted] (1992) Colorimetric determination of Xyligen potassium in Xyligen 30-F and in reaction preparations, BASF AG, Germany, Analytical Report M 92/9. unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**		

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**		
3.1.1	Enrichment		
3.1.2	Cleanup		
3.2	**Detection**		
3.2.1	Separation method	Colorimetric determination -	
3.2.2	Detector	Photometric detection at 425 nm	
3.2.3	Standard(s)	N-Cyclohexyldiazeniumdioxy-potassium-monohydrate with known purity	X
3.2.4	Interfering substance(s)	see 3.4	
3.3	**Linearity**		
3.3.1	Calibration range	0-20 mg	
3.3.2	Number of measurements	10, two different dilution series	
3.3.3	Linearity	R^2=0,99992	

3.4 Specifity: interfering substances

$FeCl_3$ gives coloured complexes with different classes of compounds, for example with phenols, compounds able to form enols, hydroxamic acids. The presence of such compounds can lead to systematical errors. The colorations produced by these classes of compounds have in part other maxima and can be identified via comparison of the UV/VIS-spectra with a standard spectrum if necessary.

The following compounds, which are structurally related to (N-Cyclohexyl-diazenium-dioxy) - potassium or his preliminary stages were examined selectively in view of possible disturbances:

Cyclohexanone
Cyclohexylamine
Cyclohexyl-hydroxylamine
Nitrocyclohexane
Cyclohexanone-oxim
Cyclohexanone-imin

After the execution of the test described in part 5 extinctions with these compounds were obtained, which are not significantly different from the blanc values. Thus, they do not cause systematic errors.

3.5 Recovery rates at different levels

Different quantities of standard solution were added to a sample with 18.2 % Xyligen-potassium and the retrieval were determined. The following values were obtained:

existent	added	given	found	retrieval
18.2 %	3.6 %	21.8 %	21.9 %	103 %
18.2 %	3.6 %	21.8 %	21.9 %	103 %
18.2 %	7.3 %	25.5 %	25.7 %	103 %
18.2 %	7.0 %	25.2 %	25.1 %	99 %

Mean: 102 %

3.5.1 Relative standard deviation 2 %

3.6 Limit of determination X

3.7 Precision

3.7.1 Repeatability 8 measurements of the sample Xyligen 30 F (batch 391) gave the following values: X

30.75 %
30.63 %
30.60 %
30.49 %
30.75 %
30.74 %
30.60 %
30.78 %
30.60 %
30.78 %

$\overline{X}$ = 30.7 %
S = 0.10
S_{rel} = 0.33 %

6 measurements of the reaction preparation had the following values:

20.99 %
20.95 %
21.22 %
20.90 %
21.11 %
21.16 %

$\overline{X}$ = 21.1 %
S = 0.13
S_{rel} = 0.60 %

3.7.2 Independent laboratory validation

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

(N-Cyclohexyl-diazenium-dioxy)-potassium constitutes in HCl-acidic solution a yellow-orange complex with Fe^{3+} ions, which can be determined photometrically at 425 nm.

The extinction of the N-Cyclohexyldiazeniumdioxy-$Fe3^{+}$-complex is at least linear in the range between 4 and 20 mg/100 ml.

4.2 Conclusion

Eight measurements of Xyligen 30 F with a K-HDO content of 30.7 % and 21.1 % respectively showed a high reproducibility of the method.

Retrieval-measurements showed that the respective values lay between 99 % and 103 %. The method can therefore be considered as valid.

4.2.1 Reliability 1

4.2.2 Deficiencies No

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure active substance**

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Dec. 2005
Materials and methods	3.2.3 Cyclohexylhydroxydiazene 1-oxide, potassium salt monohydrate with known purity 3.6 LOD ≤ 4 mg/100mL 3.7.1 Only the measurements of the sample Xyligen 30 F are of interest. The repeatability is satisfying.
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	acceptable
Remarks	none
	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A4 (4.1) **Annex Point IIA4.1**	**Analytical Methods for Detection and Identification** *impurity of a.s.: Chloride*

		1 REFERENCE	**Official use only**
1.1	**Reference**	A 4.1/02 [redacted] 2003, Determination of Chloride and Bromide by potentiometric Titration ("Bestimmung von Chlorid und Bromid durch potentiometrische Titration"), BASF AG, GKA Analytic, test method 0021/05, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	The sample will be solved or extracted in VE-water or organic solvent respectively in a mix of VE-water and organic solvent. For determinations in the lowest concentration range it is favourable to solve the sample in an organic solvent and to increase without any addition of water with 5 ml standard solution 0,001 mol/l (hydrochloride acid or NaBr)	
3.1.2	Cleanup	No data reported in the method	
3.2	**Detection**		
3.2.1	Separation method	Potentiometric Titration	
3.2.2	Detector	Silver electrode	
3.2.3	Standard(s)	External standard	
3.2.4	Interfering substance(s)	The method detects all compounds which may react with silver ions (i.e. Thiocyanate, cyanide ions, sulphide ions)	
3.3	**Linearity**		
3.3.1	Calibration range	Not applicable. The volumetric titration is an absolute method. A calibration is therefore not necessary.	
3.3.2	Number of measurements	Not applicable	
3.3.3	Linearity	Linearity is given because the summarised method is an absolute method	
3.4	**Specifity: interfering substances**	Sample material that produces under the selected test conditions halogenide-ions (Hydrolysis / Solvolysis) may lead to systematic errors. In the presence of great chloride quantities in the sample the bromide determination is characterised by a bad recovery rate (systemic error by mixed crystal-formation)	

3.5 Recovery rates at different levels

The recovery rate has been determined 11 times with different net weights of a sodium chloride sample (theoretical Chloride content. 60,66 g/100 g):

Net weight	*Date*	*Content*
35,91	24.03.1999	60,57
29,22	24.03.1999	60,74
29,29	25.03.1999	60,66
32,89	25.03.1999	60,66
27,47	26.03.1999	60,65
26,26	26.03.1999	60,67
36,31	26.03.1999	60,66
32,86	29.03.1999	60,71
69,29	29.03.1999	60,66
45,07	30.03.1999	60,61
34,65	30.03.1999	60,56

Mean value: 60,65g /100g Recovery rate: 99,98 %

Standard deviation: 0,05 g/100g

3.5.1 Relative standard deviation

Relative standard deviation: 0,08 %

3.6 Limit of determination

The maximal net weight and the minimal titration volume predetermine the limit of determination. The consumption of standard solution (minus blind value) must be greater than 1 ml. With respective net weights, a limit of determination of 1 mg/kg is reachable.

3.7 Precision

Non-entry field

3.7.1 Repeatability

Number	*Net weight*	*Consumption of Silver nitrate solution c = 0,0001 mol/l*	*Content (Cl-) mg/kg*
1	1,163	6,152	29,9
2	1,576	6,508	30,1
3	2,254	7,119	30,7
4	3,186	7,973	31,2
5	3,993	8,712	31,4
6	4,653	9,223	30,9

Mean value: 30,70 mg/kg Relative standard deviation: 1,94

Standard deviation: 0,60 mg/kg

3.7.2 Independent laboratory validation

Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

The sample will be solved or extracted in VE-water or organic solvent respectively in a mix of VE-water and organic solvent.

For determinations in the lowest concentration range, it is favourable to solve the sample in an organic solvent and to increase without any addition of water with 5 ml standard solution 0,001 mol/l (hydrochloride acid or NaBr). The resulting sample solution will be acidified with diluted sulphuric acid or diluted nitric acid and subsequently potentiometric determined. For the determination of chloride or bromide, the sample solution will be titrated with a silver nitrate standard solution by usage of a silver electrode. The mass content of chloride or bromide can be determined with the following equations:

$$w(Br):=\frac{M_{Br}\ x\ V_1\ x\ c\ x\ f\ x\ 100}{E}$$

$$w(Cl)=\frac{M_{Cl}\ x\ (V_2-V_1)\ x\ c\ x\ f\ x\ 100}{E}$$

w(Br) = mass content bromine (g/100 g)
w(Cl) = mass content chlorine
MBr = molar mass bromine (79,904 g/mol)
MCl = molar mass chlorine (35,453 g/mol)
V_1 = consummated volume of the silver nitrate solution – blind value Br (ml)
V_2 = consummated volume of the silver nitrate solution – blind value Cl (ml)
c = concentration of the silver nitrate solution
f = titre of the silver nitrate solution
E = net weight of the sample (mg)

4.2 Conclusion

The described analytical method is suitable for measuring chloride ~~or bromide ions.~~ X

4.2.1 Reliability 1

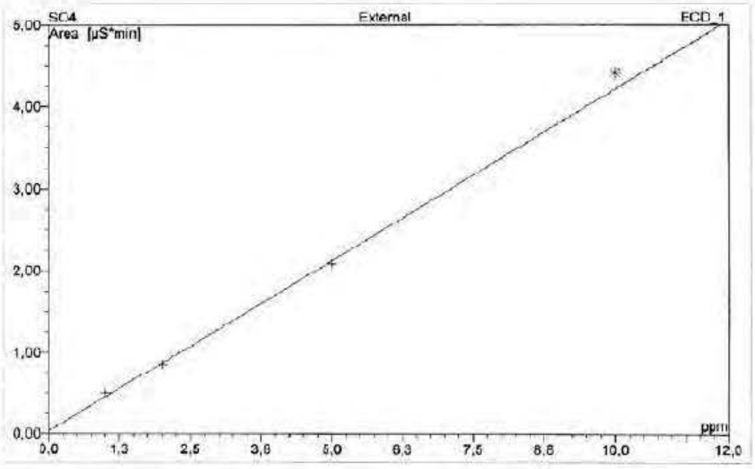
4.2.2 Deficiencies No

Section A4 (4.1)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.1	*impurity of a.s.: Chloride*

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Dec. 2005
Materials and methods	The applicant's version is acceptable
Conclusion	The described analytical method is suitable for analysing chloride
Reliability	1
Acceptability	acceptable
Remarks	none
	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A4 (4.1)
Annex Point IIA4.1

Analytical Methods for Detection and Identification
impurity of a.s.: Sulphate

		1 REFERENCE	**Official use only**
1.1	**Reference**	A 4.1/04 [redacted] 2005, Determination of Sulphate in Xyligen 30 F by Ion-chromatography, BASF AG, Competence centre Analytic, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Not performed	
3.1.2	Cleanup	Not performed	
3.2	**Detection**		
3.2.1	Separation method	Ion-Chromatography-system	
3.2.2	Detector	Conductivity detection	
3.2.3	Standard(s)	External Sulphate standard solution for calibration: ß(SO_4^{2-}) = 1000 mg/l	
3.2.4	Interfering substance(s)	The method detects all compounds which show a signal with the mentioned retention time under the described chromatographic conditions. However, in praxis there are no disturbances.	
3.3	**Linearity**		
3.3.1	Calibration range		
3.3.2	Number of measurements	6	
3.3.3	Linearity	The functional correlation between peak area and measurement	X

concentration is based on the calibration. The used measurement range is between 0,5 and 5 mg/l in the measurement solution. The working range of the method can be shifted by dilution of the measurement solution, lower sample initial weight, or larger replenishing volume to higher sulphate concentrations.

3.4 Specifity: interfering substances

The method detects all compounds which show a signal with the mentioned retention time under the described chromatographic conditions. However, in praxis there are no disturbances.

3.5 Recovery rates at different levels

The sample has been with 2 mg/l sulphate (relating to the measurement solution). The following recovery rates have been found:

No.	Initial weight / g	Conc. Measurement solution (mg/l)	Recovery rate %
1	0,8738	4,03	105
2	0,8332	3,90	104

3.5.1 Relative standard deviation

Not reported

3.6 Limit of determination

Based on an initial weight of 0,5 g and a lower concentration level of 0,5 mg mass fractions above 0,05 g/100 g are detectable.

3.7 Precision

3.7.1 Repeatability

No.	Initial weight / g	ß(SO_4^{2-}) g/100g
1	0,9654	0,109
2	0,6184	0,104
3	0,8983	0,106
4	0,7184	0,104
5	0,6372	0,103
6	0,8906	0,107

RSD: 2,1 %, mean value: 0,106 g/100g

3.7.2 Independent laboratory validation

Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Principle:
The sample will be solved with water and sulphate ions will be determined by ion chromatography with conductivity detection.

Performance:
As a basic principle double determinations will be performed.

Sample preparation and measurement:
The sample will be weighed into a 50 ml graduated flask that will be filled up with the eluant (3.2 mmol Na_2CO_3 and 1.0 mmol/l $NaHCO_3$ in water) to the marking. Afterwards the solution will be 10-times diluted with the eluant and analysed with the ion-chromatography system. The detection is performed by measurement of the Conductivity.

Section A4 (4.1) **Annex Point IIA4.1**	**Analytical Methods for Detection and Identification** *impurity of a.s.: Sulphate*

4.2 Conclusion	The method is suitable for the determination of sulphate ions in Xyligen 30 F.
4.2.1 Reliability	1
4.2.2 Deficiencies	No

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Dec. 2005
Materials and methods	Agree with the applicant's version
Conclusion	Adopt applicant's version
Reliability	1
Acceptability	acceptable
Remarks	3.3.3 Linarity: R^2=0,9998
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.1	**For pure substance**

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.1-05 [redacted] (2005) Validation of a Photometer method for the determination of K-HDO in water, [redacted], Germany, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Dr. Wolman GmbH	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**	Non-entry field	
3.1.1	Enrichment		
3.1.2	Cleanup		
3.2	**Detection**	Non-entry field	
3.2.1	Separation method	Colorimetric determination –The sample is acidified with a 5 M HCL. After that 0.5 mL of a 5 % $FeCl_3$ solution are added. This solution is measured at 425 nm against a blank containing distilled water.	
3.2.2	Detector	Photometric detection at 425 nm	
3.2.3	Standard(s)	N-Cyclohexyldiazeniumdioxy-potassium-monohydrate with known purity	X
3.2.4	Interfering substance(s)		
3.3	**Linearity**	Non-entry field	
3.3.1	Calibration range	9-180 mg/L	
3.3.2	Number of measurements	12, two different dilution series	
3.3.3	Linearity	R^2=0,99998	

3.4 Specifity: interfering substances

$FeCl_3$ gives coloured complexes with different classes of compounds, for example with phenols, compounds able to form enols, hydroxamic acids. The presence of such compounds can lead to systematical errors. The specificity of the method was determined in reference A 4.1. The colorations produced by these classes of compounds have in part other maxima and can be identified via comparison of the UV/VIS-spectra with a standard spectrum if necessary. X

The following compounds, which are structurally related to (N-Cyclohexyl-diazenium-dioxy) - potassium or his preliminary stages were examined selectively in view of possible disturbances:

Cyclohexanone
Cyclohexylamine
Cyclohexyl-hydroxylamine
Nitrocyclohexane
Cyclohexanone-oxim
Cyclohexanone-imin

After the execution of the test described in part 5 extinctions with these compounds were obtained, which are not significantly different from the blanc values. Thus, they do not cause systematic errors.

3.5 Recovery rates at different levels

Water samples spiked with K-HDO at four different levels were prepared and analysed for K-HDO. The recovery is determined by comparison of the calculated contents based on the weighed portion and of the results of the photometer- analysis.

Sample	Set point [mg K-HDO/L]	Photometer [mg K-HDO/L]	Recovery [%]
Level 1	149.7	150.4	100.5
Level 2	59.9	59.3	99.0
Level 3	15.4	15.6	101.0
Level 4	5.99	5.78	96.5

The analytically recovery ranges from 96.5 % to 100.5 %.

3.5.1 Relative standard deviation

2.02 %

3.6 Limit of detection (LOD)

The limit of detection is the lowest concentration of analyte in the sample that can be detected under the experimental conditions. The LOD is determined by preparing standard solutions at lowest concentrations at which the analyte can be reliably detected. The lowest standard solution which produces a measurable signal corresponding to the analyte is analysed 6 times. The mean value B and the standard deviation (SD) of the 6 results are calculated. The LOD is calculated by the following equation: X

$LOQ = B + (3 \times SD)$

In this study the determined LOD is 1.6 mg K-HDO /L.

3.7 Precision

Non-entry field

3.7.1 Repeatability

Solutions at four different levels are prepared and measured by photometer. The relative standard deviations are calculated.

The following RSDs are found:

5 mg K-HDO /L –level: 5.0 %

15 mg K-HDO /L –level: 1.0 %
60 mg K-HDO /L –level: 2.2 %
150 mg K-HDO /L –level: 0.2 %

with regard to the different concentration the RSD at all levels is excellent.

3.7.2	Independent laboratory validation	*Not performed*
		4 APPLICANT'S SUMMARY AND CONCLUSION
4.1	**Materials and methods**	(N-Cyclohexyl-diazenium-dioxy)-potassium constitutes in HCl-acidic solution a yellow-orange complex with Fe^{3+} ions, which can be determined photometrically at 425 nm. The extinction of the N-Cyclohexyldiazeniumdioxy-$Fe3^{+}$-complex is at least linear in the range between 5 and 180 mg K-HDO /L.
4.2	**Conclusion**	The analytically method is applicable for the determination of K-HDO in water. The linearity of the method, the specifity against relevant interfering substances and the precision are excellent. The limit of detection is determined as 1.6 mg K-HDO/L. The method can therefore be considered as valid.
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure substance**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Juli 2007
Materials and methods	3.2.3 Cyclohexylhydroxydiazene 1-oxide, potassium salt monohydrate with known purity 3.6 Limit of determination = B + (3 x SD) = 1.6 mg/L Limit of quantification = A + (10 x SD) = 8.7 mg/L B … mean value standard solution measured at LOQ concentration (based on preliminary studies). The solution is analysed 6 times. 3.6 The specificity of the method was determined in reference A 4.1.
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	acceptable
Remarks	none
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure substance**

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.1-06 Concentration control analysis of N-Cyclohexyl-diazeniumdioxy-potassium in non Chlorinated Charcoal filtered tap water ([redacted], mixed with deionized water, page 76 ff. From A 7.4.3.2.11, [redacted] (2005) N-Cyclohexyl-diazeniumdioxy-potassium –Juvenile Growth Test in the Zebra Fish (Danio rerio) in a flow through system, [redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Dr. Wolman GmbH	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	Yes	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**	Non-entry field	
3.1.1	Enrichment		
3.1.2	Cleanup		
3.2	**Detection**	Non-entry field	
3.2.1	Separation method	HPLC with external standard	
3.2.2	Detector	UV detection at 229 nm	X
3.2.3	Standard(s)	N-Cyclohexyldiazeniumdioxy-potassium-monohydrate standard with known purity, stock solutions are freshly prepared with distilled water (10mg/L). As vehicle non chlorinated charcoal filtered tap water ([redacted]) mixed with deionized water is used.	X
3.2.4	Interfering substance(s)	No interfering substances are reported	
3.3	**Linearity**	Non-entry field	
3.3.1	Calibration range	Under the described chromatographic conditions, aliquots (50 µL) of the standards were analyzed by HPLC. Record peak response was recorded as area under the curve. Each sample was analyzed twice. Means were used for quantification. Linearity between concentration and area under the curve was given in the range of the analysis. The calibration curve is shown in Figure 1.	

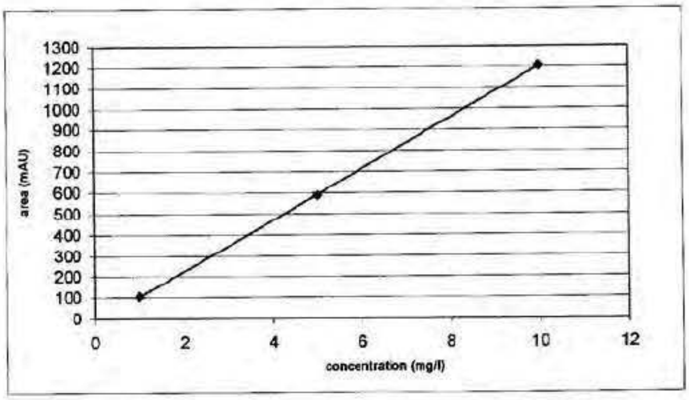


Fig. 1: Typical standard calibration curve

3.3.2	Number of measurements	25, two different dilution series
3.3.3	Linearity	Linearity between concentration and area under the curve was given in the range of the analysis.
3.4	**Specifity: interfering substances**	HPLC chromatography is used as separation technique. The method allows the selective determination of K-HDO in tap water. Co-eluting compounds will lead to higher results of analysis
3.5	**Recovery rates at different levels**	The mean values of K-HDO were found to be in the range of 52.3 – 124.5 % of the nominal concentration. In the two highest concentrations the measured concentrations were lower than expected in most of the retain samples analyzed. At the end of the exposure, the values of the higher concentrations ranged from 82.2 –87.2 %.
3.5.1	Relative standard deviation	-
3.6	**Limit of Quantification (LOQ)**	The limit of quantification was determined as 0.03 mg/L.
3.7	**Precision**	Non-entry field
3.7.1	Repeatability	Solutions at four different levels are prepared and measured by HPLC-UV twice. The relative standard deviations are calculated. The following RSDs are found: 1.1 mg K-HDO /L –level: 0.5 % 0.33 mg K-HDO /L –level: 0.25 % 0.1 mg K-HDO /L –level: 0.18 % 0.033 mg K-HDO /L –level: 0.3 % with regard to the different concentration the RSD at all levels is excellent.
3.7.2	Independent laboratory validation	*Not performed*

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure substance**

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

The analytical method is based on a HPLC with external calibration. The following parameters are given in detail:

Column: Discovery C 18 soil, 125 x 3mm. ID 5 µ.

Eluant: 35 % acetonitrile + 0.5 M sulphuric acid

65 % doubly distilled water + 0.5 M sulphuric acid

Injection volume: 50 µL

Temp.: ambient

Detection: UV, 227 nm

4.2 Conclusion

The analytically method is applicable for the determination of K-HDO in water. The linearity of the method and the precision are given in the range of the analysis. The limit of quantification is determined as 0.03 mg K-HDO/L.

The method can therefore be considered as valid.

4.2.1 Reliability 1

4.2.2 Deficiencies No

Section A4 (4.1) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1 **For pure substance**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	3.2.2. UV detection at 227 nm 3.2.3 Cyclohexylhydroxydiazene 1-oxide, potassium salt monohydrate with known purity
Conclusion	Agree with the applicant's version
Reliability	1
Acceptability	acceptable
Remarks	none
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2

K-HDO, soil

For soil

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/01 [redacted] (2004) Validation of a HPLC method for the determination of K-HDO in soil, [redacted], Germany Analytical Report, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Dr. Wolman GmbH	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Extraction with methanol/buffer solution by stirring at room temperature	
3.1.2	Cleanup		
3.2	**Detection**		
3.2.1	Separation method	HPLC/UV (DAD), C18 soil, 150 mm length, 4,6 mm diameter	
3.2.2	Detector	UV-detector, 229 nm	
3.2.3	Standard(s)	K-HDO standard, external	
3.2.4	Interfering substance(s)	Under the described experimental conditions, no interferences have been observed until now when analysing soil samples.	
3.3	**Linearity**		
3.3.1	Calibration range	2-50 mg/l K-HDO	
3.3.2	Number of measurements	6	X
3.3.3	Linearity	r^2= 0,99957	
3.4	**Specificity: interfering substances**	The accuracy of the method has been demonstrated with the still good recovery rates. Under the described experimental conditions, no interferences have been observed until now when analysing soil samples.	
3.5	**Recovery rates at different levels**	The analytical recovery ranges from 875 to 90 % for the level of about 1 mg K-HDO/g soil and from 71% to 94 % for the level of about 0.16 mg / K-HDO/g soil.	X

3.5.1	Relative standard deviation		X
3.6	**Limit of determination**	The limit of detection amounts to 0.025 mg K-HDO/g soil.	X
3.7	**Precision**		
3.7.1	Repeatability	The relative standard deviation amounts to 2.3 % for the higher level and 10.3 % for the lower level.	X
3.7.2	Independent laboratory validation	n.a.	
		4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1	**Materials and methods**	The used HPLC-UV method is a suitable method for the detection of K-HDO after extraction from soil (pH 5 and 7) with a methanol/buffer solution.	
4.2	**Conclusion**	The precision and the reproducibility of the method are sufficient. Therefore the method can be considered as valid.	
4.2.1	Reliability	1	
4.2.2	Deficiencies	No	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Oct. 2005
Materials and methods	3.3.2 Number of measurements Three solutions of K-HDO with different concentrations (0.474, 0.888 and 3.552mg K-HDO/L) were measured (six times each). 3.5 Recovery rates at different levels The analytical recovery ranges from 87% to 90 % for the level of about 1 mg K-HDO/g soil and from 71% to 94 % for the level of about 0.16 mg K-HDO/g soil. The main value of all recovery rates is 85%. 3.5.1 Relative standard deviation 8.2% 3.6 Limit of determination From the study an LOQ of 0.26 mg K-HDO / g soil can be estimated. 3.7.1 Repeatability Two soil samples containing 1 mg K-HDO / g soil and three soil samples containing 0.16 mg K-HDO / g soil are extracted and analysed by HPLC-UV for K-HDO. The relative standard deviation amounts to 2.3 % for the higher level and 10.3 % for the lower level.
Conclusion	Agree with the applicant's version with the amendments given above
Reliability	1
Acceptability	acceptable
Remarks	-

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.3) **Annex Point IIIA-IV.1**	**Analytical Methods for Detection and Identification** **For food/feedstuffs**

	Justification for non-submission of data	**Official use only**
Other existing data [☐] Limited exposure [☒]	Technically not feasible [☐] Scientifically unjustified [☐] Other justification [☐]	
Detailed justification:	A contact of wood preservatives with food and feeding stuff is excluded. Therefore, a study in food and feedstuffs is not required.	X
Undertaking of intended data submission [☐]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Oct 2005	
Evaluation of applicant's justification	Any exposition of food and feeding stuff to wood preservatives via the environment is not expected. Furthermore, the treated wood is not intended to be in contact with food and feeding stuff. Therefore, the treated wood must not be used for furniture which may come in contact with food and feeding stuff.	
Conclusion	The justification is acceptable.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE (SPECIFY)	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A5 — Effectiveness against target organisms and intended uses

Subsection (Annex Point)			**Official use only**
5.1	**Function (IIA5.1)**	*K-HDO is a wood preservative with a broad spectrum of action against wood destroying Basidiomycetes* *III.1 – Fungicide*	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	*Wood destroying fungi (brown rot, white rot, softrot:* *I.1 – Fungi* *I.1.1.1 – Basidiomycetes*	X
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	*K-HDO is used for the protection of wood and wood based panels / wood composites (e.g. plywood and particle boards)* *VII.1 – preventive* *The effectiveness of the active substance K-HDO has been demonstrated both against softwood and hardwood destroying basidiomycetes (see also § 5.3).*	X
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	*Fungitoxic effects. K-HDO inhibits enzymatic activity in fungi.* *The efficacy of K-HDO can be deduced from the tests carried out with different softwood and hardwood destroying basidiomycetes. The results are summarised in table 5.3.* The results confirm that K-HDO is effective against both white and brown rot fungi.	X

5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	*The active substance K-HDO is used in the wood preservation area as a 30% aqueous solution (Xyligen 30 F). In order to achieve in the treated wood the toxic values as determined in the efficacy tests, treatment solutions ranging from 0,2 – 3,5 % are necessary depending on the timber species.* *For the treatment of particle boards, 0,8 – 1,2 % Xyligen 30 F / dry particles is necessary (see also § 5.3 of Doc III B.* *For each product type (PT1 to PTn) given in section 5.5* Remark: The limit values given in the doc III B determined according to DIN 52176 were mentioned in an earlier Dr. Wolman internal document. Unfortunately there is no test report available.	X
	PT1		
	PTn		
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	*Fungitoxic effect* *III.1 - fungicide* *III.1.1 – Inhibition of metabolism*	
5.4.2	**Time delay**	*Immediately after treatment the wood or wood composites are protected against fungal attack*	
5.5	**Field of use envisaged (IIA5.5)**	*Protection of wood and wood composites (e.g. plywood and particle boards) against wood-destroying fungi* *IV.1 – indoor use* *IV.1.2 – use class 2* *IV.2 – outdoor use* *IV.2.1 – use class 2*	X
	MG01: Disinfectants, general biocidal products MG02: Preservatives MG03: Pest control MG04: Other biocidal products Further specification	*Product types PT08*	
5.6	**User (IIA5.6)**		

	Industrial	*Industrial and professional users only* *V.2 – professional* *V.3 – specialised professional*
	Professional	*Industrial and professional users only* *V.2 – professional* *V.3 – specialised professional*
	General public	*K-HDO is not intended to be used by the general public*
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**	
5.7.1	**Development of resistance**	*K-HDO is used as wood preservative for many years. No cases with resistance have been reported for this group of fungicides*
5.7.2	**Management strategies**	*Not required*
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	*Approx. 120 tonnes per year*

Section A5 Effectiveness against target organisms and intended uses

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07.06.2005
Materials and methods	**5.3.1. Effects on target organisms** The EN 113 and the former German version DIN 52176 are standardised methods to prove protective activity against wood destroying basidiomycetes. The ENV 12038 is the presently standardised test to prove the resistance of wood based panels and wood composites against wood destroying basidiomycetes. The submitted BAM-tests from 1972 resp. 1987 on preventive effectiveness against basidiomycetes are adequately described for assessment.
Conclusion	**5.2.1. Organism(s) to be controlled (IIA5.2)** The stated control of soft rot fungi was not supported by efficacy test data. **5.2.2. Products, organisms or objects to be protected** Application with wood is not supported. Only protection of wood composites (particle boards) against attack by wood-destroying fungi is supported (see doc IIIB5). The restriction of the applicant "for outdoor use only with an additional coating" is not necessary from point of view of the efficacy assessment **5.3.1. Effects on target organisms** The EN 113 test were carried out 1983 in the mycological laboratory of the applicant for brown rot fungi Poria placenta and Coniophora puteana on pine sapwood and for the white rot fungus Coriolus versicolor on beech. The test data show a remarkably higher toxic value for the white rot fungus compared to the brown rot fungi (at least 8 : 1). The test report is signed with the date 20.09.2004 by the present head of biological testing (Ref. A 5.3). In this test report some essential details are not included: mass losses of the treated specimens and associated untreated control specimens. **5.3.2 Likely concentrations at which the A.S. will be used** The stated range of treatment solutions for treatment of wood are derived from the data in EN 113 test (Ref. A 5.3). The toxic values given in doc III B are not supported by a test report or other supplementary data. The stated range of concentration of Xyligen 30F for treated particle boards is derived from the results of BAM-tests (Ref. A 5.10.2/01 - 02). The tests were carried out with particle boards treated with Xyligen 25F, containing 25% K-HDO without other active ingredients. The test data showed that boards with 0,92% Xyligen 30 F/dry particle board were resistant against basidiomycetes.
Reliability	2 (BAM-tests of panels against basidiomycetes) 3 (EN 113 Ref. A 5.3) 4 (stated toxic values in doc III B para 5.10.2 without test report)

Section A5 Effectiveness against target organisms and intended uses

Acceptability	It can be accepted that the test results indicate the effectiveness of the active ingredient for use as fungicidal component in preventive wood preservatives for wood based materials and wood composites. The indicated minimum dosage of 0,8 % (w/w)) Xyligen 30 F/ dry particles for **particle boards** of is not acceptable, since sufficient efficacy was proven only with an application rate of at least 0,92% (w/w) Xyligen 30 F/dry particle board. With a usual content of solid resin and hydrophobic substances of 10% this dosage results to a minimal application rate of 1,02% (w/w) Xyligen 30 F/dry particles. The minimal application rate of 0,92% (w/w) Xyligen 30F/dry particle boards equals to 5,5 - 7,4 kg Xyligen 30F/ m^3 dry particle boards with density range up 600 to 800 kg/m^3.. The experimental data of impregnated **wood** are not acceptable.
Remarks	The stated surface treatment of wood was not supported by efficacy test results.

	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
Include respective code(s) for function type(s) given in section 5.1	*Include respective code(s) for product type(s) given in section 5.5*	*Describe specification if deviating from that given in section 2*	*Specify species, strain, sex, weight, growth stage etc. as appropriate*	*Shortly describe test system and application method used in the tests*	*Shortly describe test conditions including concentrations applied and exposure time*	*Describe relevant results; quantify the effects on target organisms; indicate the dependence on the concentrations of the A.S. and the possible existence of a threshold concentration.* *Also describe if results indicate the mode of action and/or the development of resistance.*	*Only author(s) and year of publication/ report; full bibliographic data in footnote*
III.1	PT08	K-HDO	Poria placenta	EN 113	0,05 – 0,10 – 0,25 – 0,50 – 1,00 % (m/m) Duration : 16 weeks Ageing : without Pine sapwood	< 0,34 kg/m^3	[redacted] *– 2004* *Ref. 5.3*
III.1	PT08	K-HDO	Coniophora puteana	EN 113	0,05 – 0,10 – 0,25 – 0,50 – 1,00 % (m/m) Duration : 16 weeks Ageing : without Pine sapwood	< 0,34 kg/m^3	[redacted] *– 2004* *Ref. 5.3*
III.1	PT08	K-HDO	Coriolus versicolor	EN 113	0,05 – 0,10 – 0,25 – 0,50 – 1,00 % (m/m) Duration : 16 weeks Ageing : without Beech	1,49 – 2,92 kg/m^3	[redacted] *– 2004* *Ref. 5.3*
III.1	PT08	K-HDO	Poria placenta	EN 113 + EN 84	0,05 – 0,10 – 0,25 – 0,50 – 1,00 % (m/m) Duration : 16 weeks Ageing : leaching Pine sapwood	1,82 – 3,41 kg/m^3	[redacted] *– 2004* *Ref. 5.3*
III.1	PT08	K-HDO	Coniophora puteana	EN 113 + EN 84	0,05 – 0,10 – 0,25 – 0,50 – 1,00 % (m/m) Duration : 16 weeks Ageing : leaching Pine sapwood	1,70 – 3,52 kg/m^3	[redacted] *– 2004* *Ref. 5.3*
III.1	PT08	K-HDO	Coriolus versicolor	EN 113 + EN 84	0,05 – 0,10 – 0,25 – 0,50 – 1,00 % (m/m) Duration : 16 weeks Ageing : leaching	≥ 6,12 kg/m^3 This means that the threshold value is	[redacted] *– 2004* *Ref. 5.3*

					Beech	about 6,12 kg/m^3 or only insignificantly above this value.	

*) References:

List the references cited in alphabethical order with full bibliographic data (Author(s) (year) Title. Source)

Ref. A 5.3 : Effectiveness of K-HDO against wood destroying fungi – Dr. Wolman GmbH - 2004