Product Assessment Report

Xyligen 30 F

July 2011

Internal registration/file no:	BMLFUW-UW.1.2.5/118-V/2011
Authorisation/Registration no:	AT/2011/Z/00003/08
Granting date/entry into force of authorisation/ registration:	30.08.2011
Expiry date of authorisation/ registration:	30.06.2020
Active ingredient:	Cyclohexylhydroxydiazene 1-oxide, potassium salt (short: K-HDO)
Product type:	PT 8 (Wood preservatives)

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Dr. Wolman GmbH (BASF Group)
Address:	Dr. Wolman-Str.31-33
City:	Sinzheim
Postal Code:	76547
Country:	Germany
Telephone:	(+49) 7221-800-0
Fax:	(+49) 7221-800210
E-mail address:	wendelin.hettler@wolman.de rene.schwartz@wolman.de

1.1.1 Person authorised for communication on behalf of the applicant

Name:	not assigned / see 1.1 Applicant
Function:	-
Address:	-
City:	-
Postal Code:	-
Country:	-
Telephone:	-
Fax:	-
E-mail address:	-

1.2 Current authorisation holder[1]

Company Name:	no existing authorisation available
Address:	-
City:	-
Postal Code:	-
Country:	-
Telephone:	-
Fax:	-
E-mail address:	-
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	-

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[1] Applies only to existing authorisations

1.3 Proposed authorisation holder

Company Name:	Dr. Wolman GmbH (BASF Group)
Address:	Dr. Wolman-Str.31-33
City:	Sinzheim
Postal Code:	76547
Country:	Germany
Telephone:	(+49) 7221-800-0
Fax:	(+49) 7221-800210
E-mail address:	wendelin.hettler@wolman.de rene.schwartz@wolman.de
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No

1.4 Information about the product application

Application received:	2010-06-28
Application reported complete:	2010-10-18
Type of application:	authorisation
Further information:	no

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Xyligen 30 F
Manufacturer's development code number(s), if appropriate:	Xyligen 30 F, Xyligen K 30 F, K-HDO techn. 30 %
Product type:	PT 8 (wood preservative)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	30%w/w active substance Cyclohexylhydroxydiazene 1-oxide, potassium salt (short: K-HDO)
Formulation type:	ready-to-use preservative (aqueous solution)
Ready to use product (yes/no):	yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name:	no

or **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	yes

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Preventive protection of wood composites predominately based on softwood against attack by wood rotting fungi in use class 2 situations and for boards for scaffolding only with additional coating in use class 3.1 situations
Target organisms:	Wood rotting basidiomycetes (brown rot fungi, white rot fungi)
Category of users:	Industrial (professional)
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	Generally mixing with glue; in special cases added by spaying in closed systems to wooden particles; the minimum dosages are 0.92 % (w/w) product / dry particle board resp. 7.5 kg product / m³ plywood, oriented strandboard (OSB) or laminated veneer lumber (LVL)
Potential for release into the environment (yes/no):	no
Potential for contamination of food/feedingstuff (yes/no)	no
Proposed Label:	As stipulated in the Austrian authorisation decision directed to the Applicant
Use Restrictions:	See chapter 3 of this document

1.5.3 Information on active substance(s)[2]

Active substance chemical name:	Cyclohexylhydroxydiazene 1-oxide, potassium salt
CAS No:	66603-10-9
EC No:	not attributed
Purity (minimum, g/kg or g/l):	977 g/kg
Inclusion directive:	2008/80/EC
Date of inclusion:	01.07.2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	yes

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[2] Please insert additional columns as necessary

Manufacturer of active substance(s) used in the biocidal product:	BASF SE
Company Name:	BASF SE
Address:	Carl-Bosch-Straße 38
City:	Ludwigshafen
Postal Code:	67056
Country:	Germany
Telephone:	(+49) 621-60-0
Fax:	not available
E-mail address:	not available

1.5.4 Information on the substance(s) of concern[3]

Substance chemical name	not applicable
CAS No:	not applicable
EC No :	not applicable
Purity (minimum, g/kg or g/l):	not applicable
Typical concentration (minimum and maximum, g/kg, or g/l):	not applicable
Relevant toxicological/ecotoxicological information:	not applicable
Original ingredient (trade name):	not applicable

1.6 Documentation

1.6.1 Data submitted in relation to product application

For information on new submitted data, please see Annex Chapter 2 of the product assessment report.

1.6.2 Access to documentation

No letter of access is required.

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[3] Please insert additional columns as necessary

2 Summary of the product assessment

2.1 Identity related issues

<u>Result of a check for equivalence/identity of the active substance listed in Annex I of 98/8/EC and the active substance(s) in the product:</u>

The active substance contained in the product Xyligen 30 F is the very same as the active substance listed in Annex I of 98/8/EC (same source). Therefore, no equivalence check is required.

<u>Composition of the product including identity of every substance of concern:</u>

The biocidal product is the same as the representative biocidal product accompanying the Annex I inclusion.

Result of a check of sameness:

		Biocidal product presented in the PAR			**Representative biocidal product accompanying the Annex I inclusion**		
Trade name		Xyligen 30 F			Xyligen 30 F		
Manufacturer´s development code number(s)		Xyligen 30 F, Xyligen K 30 F, K-HDO techn. 30%			Xyligen 30 F, Xyligen K 30 F, K-HDO techn. 30%		
Ingredients of preparation		**Name**	**Function**	**Con-tent**	**Name**	**Function**	**Con-tent**
	1	Cyclohexylhydroxy-diazene 1- oxide, potassium salt	active substance	30% w/w	Cyclohexylhydroxy-diazene 1- oxide, potassium salt	active substance	30% w/w
	further	Confidential			Confidential		
Physical state of preparation		liquid			liquid		
Nature of preparation		ready-to-use preservative (aqueous solution)			ready-to-use preservative (aqueous solution)		

<u>Special requirement for Wood composites used in use class 3 – Composition of the coating:</u>

Wood composites used in **use class 3.1** are only allowed with a coating. In the leaching study, the coating was described as a “water and abrasion resistant phenolic resin coating”. The film coating has a weight of > 120 g/m². The abrasion resistance is > 380 revolutions according to DIN 53799.
The top coating is a **<u>phenolic surface coating</u>**. The main components are paper (approx. 95%), phenolic resin (approx. 2 – 5%) and additives e.g. pigments, release agent (approx. 1 – 3%). The phenolic resin contains the following constituents: phenol, urea, formaldehyde and sodium hydroxide. The phenolic surface coating can be described as a resin impregnated paper which is applied to the plywood panels under heat and pressure. During the manufacturing process, the resin fully polymerises/cures and forms a 3-dimensional network. As indicated previously, the surface coating used is based on phenolic resin and paper.
The most important physicochemical property for the “functioning” of the top coating is the reduction of the moisture absorption. The moisture absorption is typically reduced to approx. 100 g/m² per 7 days dipping whereas the panel is fully exposed to water. Moreover the mechanical stability is described by an abrasion resistance > 380 revolutions acc. to DIN 53799.

2.2 Classification, labelling and packaging

Under this heading the assessment of the classification, labelling and packaging should be summarised. Further, any result of the assessments made under the following headings that require recommendations or restrictions appearing on the label should be summarised here.

It should be noted that labelling of biocidal products goes way beyond the requirements of directive 19999/45/EC or regulation 1272/2008 (in the future) but is regulated in Art. 20 of directive 98/8/EC. Especially, the points a) - m) of Art. 20 (3) need to be addressed here in detail.

2.2.1 Harmonised classification of the biocidal product

Please see Annex Chapter 1 of the product assessment report

2.2.2 Labelling of the biocidal product

Please see Annex Chapter 1 of the product assessment report

2.2.3 Packaging of the biocidal product

200 l drums
640l l (Intermediate Bulk Container)
1000 l (Intermediate Bulk Container)

Appropriate container material: PE or PE inliner.

Size of the label:

Volume of packaging between 50 l and 500 l:	min. 105 mm × 148 mm
Volume of packaging greater than 500 l:	min. 148 mm × 210 mm

If filled in tank trucks, the law in force concerning transport has to be observed.

2.3 Physico/chemical properties and analytical methods

If new data/information about the physical/chemical properties as well as analytical methods for the product or for the active substance(s) has been received compared to the Annex I CAR it should be assessed and the results of the assessment(s) summarised here. Further, if there is need for a risk characterisation to be performed this should be summarised under this heading.

If no new studies have been submitted a very short summary of the physical/chemical properties and analytical methods for the product/active substance(s) can be presented here which could be copied from the assessment report or from the CAR[1] on the active substance(s). Should however co-formulants influence the properties of the product this must of course be illustrated in the summary.

2.3.1 Physico-chemical properties

Table 1: Physico-chemical properties of the active substance:

	Method/ Guideline	Purity/Specification	Result	Reference
Melting point	*[The table only needs to be filled in, if no letter of access has been submitted for the active substance.]*			
Boiling point				
Relative density				
Vapour pressure				
Henry's Law constant				
Physical state				
Colour				
Odour				
Water solubility				
Dissociation constant				
Solubility in organic solvents				
Stability				
Partition coefficient n-octanol/water				
Thermal stability				
Flash-point				
Surface tension				
Viscosity				
Explosive properties				
Oxidizing properties				
Reactivity towards container material				

Table 2: Physico-chemical properties of the biocidal product:

	Method	Purity/Specification	Results	Reference
Physical state and nature	Visual inspection;	100 % Xyligen 30 F	liquid	Doc. III-B 3; Study B 3.1.
Colour	Visual inspection;	100 % Xyligen 30 F	yellowish to brownish, clear	Doc. III-B 3; Study B 3.1.

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[1] Competent Authority Report

	Method	**Purity/Specification**	**Results**	**Reference**
Odour	Company's statement	100 % Xyligen 30 F	characteristic	Doc. III-B 3; Study B 3.1.
Explosive properties	Company's statement	purified K-HDO (solid)	The formulation does not contain any components that have explosive properties. Furthermore, there are no structural indications of explosivity. The formulation is a diluted aqueous solution and not likely to undergo exothermic decomposition.	Doc. III-B 3; Study B 3.2.
Oxidizing properties	Company's statement	purified K-HDO (solid)	The formulation does not contain any components that have oxidising properties. Moreover, there are no structural indications of oxidising potential.	Doc. III-B 3; Study B 3.2.
Flash point	Company's statement	purified K-HDO (solid)	K-HDO powder (purity 99.8%w/w, monohydrate) is considered highly flammable. Anyhow, Xyligen 30 F, which is a 30 % aqueous solution of K-HDO, can be regarded as not flammable due to the 70 % water content of the formulation.	Doc. III-B 3; Study B 3.2.
Autoflammability	Company's statement	purified K-HDO (solid)	The relative self-ignition temperature of the purified active substance is 250 °C.	Doc. III-B 3; Study B 3.2.
Other indications of flammability	n.a.	n.a.	n.a.	n.a.
Acidity / Alkalinity	Cipac MT 75 ASTM 70-77;	K-HDO as 1 %w/w aqueous solution	pH = 8.23 at 20°C	Doc. III-B 3; Study B 3.1.
Relative density / bulk density	OECD Guideline 109; DIN 53217 Part 55 (oscillation method)	100 % Xyligen 30 F	1.13 g/cm	Doc. III-B 3; Study B 3.6.
Storage stability – stability and shelf life:Effects of temperature	CIPAC MT 46, CIPAC MT 39	100 % Xyligen 30 F	Xyligen 30 F is stable at least for 14 days at 54 °C and at 0°C; the storage temperature should not be allowed to drop below –12 °C as otherwise Xyligen 30 F may crystallise	Doc. III-B 3; Study B 3.7/01. Doc. III-B 3; Study B 3.7/02.
Storage stability – stability and shelf life:Effects of light	Company's statement	100 % Xyligen 30 F	When exposed to UV radiation for 72 h, HDO is not stable. (Degradation: 80 – 90%)	
Storage stability – stability and shelf life:Reactivity towards container material	Company's statement	100 % Xyligen 30 F	Xyligen 30 F is stable in the original containers for several years. The shelf-life was tested for the following periods: 10, 16, 28, 32 months; Company statement: Xyligen 30	Doc. III-B 3; Study B 3.7/03.

	Method	**Purity/Specification**	**Results**	**Reference**
			F is compatible with the stated packaging material: • 200 L metal-polydrums with PE-inliner • IBC container, 1000 L with PE inside-box	
Technical characteristics in dependence of the formulation type	DIN 53902 part 1	100 % Xyligen 30 F	No foaming properties	Doc. III-B 3; Study B 3.8.
Compability with other products	Company's statement	100 % Xyligen 30 F	Xyligen 30 F is instable in the presence of acids	Company's statement
Surface tension	COUNCIL REGULATION (EC) No 440/2008, ANNEX Part A, method A.5.	100 % Xyligen 30 F	72.4 mN/m at 20 °C (concentration of test solution 1 g/L) not surface active	Doc. III-B 3; Study B 3.10
Viscosity	OECD Guideline 114 DIN 53019;	100 % Xyligen 30 F	4.6 mPa s at 20 °C 3.4 mPa s at 40 °C	Doc. III-B 3; Study B 3.11
Particle size distribution	Company's statement	100 % Xyligen 30 F	Not necessary because Xyligen 30 F is liquid	Company's statement

2.3.2 Analytical methods

2.3.2.1 Analysis of active substance as manufactured

As the active substance stems from the same source as the active substance evaluated under Directive 98/8/EC for Annex I listing, and as the biocidal product corresponds to the representative biocidal product evaluated under Directive 98/8/EC for Annex I listing of K-HDO, reference is made to the final Competent Authority Report and the Assessment Report accompanying the Annex I entry.
Additionally submitted data/information for the product or for the active substance compared to the Annex I CAR are assessed and summarised below.

2.3.2.2 Formulation analysis

As in this case the active substance as manufactured (KHDO as 30% aqueous solution) and the formulation (Xyligen 30 F) are identical and therefore have the exactly equal and alike composition, please see 2.3.2.1 of this document section for information on the formulation analysis.

2.3.2.3 Residue analysis

As the active substance stems from the same source as the active substance evaluated under Directive 98/8/EC for Annex I listing, and as the biocidal product corresponds to the representative biocidal product evaluated under Directive 98/8/EC for Annex I listing of K-HDO, reference is made to the final Competent Authority Report and the Assessment Report accompanying the Annex I entry.
Additionally submitted data/information for the residue analysis compared to the Annex I CAR are assessed and summarised below.

Table 2.3.2.3-1: Residue analysis

Sample	**Test subst.**	**Analytical method**	**Fortification range and Number of measurements**	**Linearity (R^2, [-])**	**Specificity**	**Recovery rate (%)**			**LOQ**	**Reference**
						Range	Mean	Rel. St. dev.		
Leachate	K-HDO	HPLC-UV with external standard (229 nm)	0.1 – 1.0 mg/L	0.9965	Not reported in the study	-	-	-	0.05 mg/L	Doc III-B.7; Study B 7.1/02

2.4 Risk assessment for Physico-chemical properties

No new data/information on Physico-chemical properties has been submitted for the product or for the active substance(s). As the active substance originates from the same source as the active substance evaluated under Directive 98/8/EC for Annex I listing, and as the biocidal product corresponds to the representative biocidal product evaluated under Directive 98/8/EC for Annex I listing of K-HDO, please consult the final Competent Authority Report and the Assessment Report accompanying the Annex I entry.

2.5 Effectiveness against target organisms

The intended use of Xyligen 30 F is the prevention of fungal growth (*basidiomycetes*) in wood composites.

The former submitted BAM-tests on treated particle boards indicate preventive action of Xyligen 30 F against wood rotting fungi (brown rot fungi, white rot fungi). One of the tests was carried out after long term storage. Therefore Xyligen 30 F can be used as a wood preservative for adhesive mixing process of wood composites for use class 2. The wood composites should be predominantly based on softwood.
The recommended minimum dosage is 1.0 % (w/w) Xyligen 30 F /dry particles or 0.30% K-HDO/ dry particles, resulting in a minimum dosage of 0.92 % (w/w) Xyligen 30 F/ dry particle board. This dosage equals to 5.5 – 7.4 kg Xyligen 30F/ m³ dry particle boards with a density range of 600 to 800 kg/m³.

Additional information and detailed data to the former submitted study IIIB 5.10.2/03 (efficacy test of Xyligen 30F against brown rot and white rot fungi in plywood) improve the quality of the study substantially. Therefore acceptable and valid data for the brown rot fungus *Coniophora puteana* and the white rot fungus *Coriolus versicolor* are presented. For the spruce- and spruce/birch-plywood the requirements of ENV 12038 were fulfilled in regard to resistance. The study IIIB 5.10.2/06 present acceptable and valid ENV 12038 test data of treated pine/birch-plywood and indicates the fungicidal effectiveness of Xyligen 30F in this combined plywood.
Therefore Xyligen 30 F can be used as a wood preservative for adhesive mixing process of softwood-plywood, spruce/birch-plywood, pine/birch-plywood, OSB (oriented strand board) and LVL (laminated veneer lumber) for use class 2. The OSB and LVL must be based on softwood. Coated plywood boards for scaffolding can also be used in use class 3.1, because these film coatings form a barrier and prevent leaching of active substance, as proved by leaching test.
The recommended minimum dosage is 7.5 kg Xyligen 30F/m³ plywood, OSB and laminated veneer lumber. The thickness of veneer layers in softwood-plywood is limited to 2.5 mm for outer veneer layers and 3.0 for inner veneer layers. For the spruce/birch-plywood and the pine/birch-plywood the veneer layers are limited to 1.8 mm and for LVL to 2.5 mm.

2.5.1 Dose / mode of action / known limitations / resistance

For details on dose (acceptable intended use), please see chapter 2.6 of this document.

The likely mode of action is via electrophilic and radical reactions with thiol-containing enzymes resulting in inhibition of cell respiration and metabolism.

The applicant reported that no occurrence of resistance is known.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Description of the accepted intended use(s):

Use classes PT 08	Formulation		Applied amount per treatment			Remarks
	Type	Conc. of a.s.	Method	kg as/m³ wood-composite		
				min.	max.	
2[1]	Xyligen 30 F	30%	Wood composites (e.g. Particleboards)	1.8	2.6	Preventive treatment
2[1]	Xyligen 30 F	30%	Wood composites (e.g. Plywood, Oriented strandboard (OSB) and Laminated Veneer Lumber (LVL))	2.25	2.85	Preventive treatment
3[2]	Xyligen 30 F	30 %	Coated wood composites[3]	2.25	2.85	Preventive treatment

[1] Use class 2: wood under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting

[2] In use class 3, Xyligen 30 F is only used for the treatment of boards for scaffolding and only with an additional coating. The coating prevents leaching into the environment.

[3] In use class 3.1 only film coated plywood boards used for scaffolding are permitted.

Description of application processes:

General

Xyligen 30 F is applied to timber chips or veneers during manufacturing of the boards (wood composites) in industrial scale process units where the wood material is processed to the requirements of the individual types of engineered wood products. This can include drying, cutting etc.

Preparation of preservative /resin mixture

Xyligen 30 F is delivered in bulk containers or in tank trucks. 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. Cleaning of the Xyligen 30 F tanks or the pipelines does not occur. These storage tanks for the resin as well as storage tanks for preservative and additional chemicals e.g. hardener, water etc. are connected to processing units by additional transfer lines. Mixing of preservative and resin is fully automatic and controlled by gravimetrical or volumetrical methods and computer systems.

Treatment Process

The most common method in Europe is the 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 (e.g. by separate nozzles) if interfering contact between preservative and resin has to be avoided. In both cases, the application of the preservative is incorporated in an automatic manufacturing process and does not require any additional equipment or direct involvement of personnel. Subsequent to glue application the engineered wooden products will be compressed. 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.

Particle boards and Oriented strandboard (OSB)

Chips for e.g. 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.

Plywood and Laminated Veneer Lumber (LVL)

Plywood is manufactured through a process of laminating thin sheets of veneer together. The glue-preservative-mix for plywood is applied between the individual veneers by rolls.

2.6.2 Assessment of exposure to humans

If new exposure studies have been submitted they should be evaluated and the result can be presented here. Or, even if new studies have not been submitted the exposure pattern might need to be assessed and discussed here.

As the biocidal product is the same as the representative biocidal product accompanying the Annex I inclusion, only the changes in the assessment are described in detail. Already agreed, unchanged results are only summarised. For further details, please see Competent Authority Report of K-HDO PT 8.

In comparison to the Competent authority report accompanying the Annex I inclusion, the max. applied amount per treatment is 2.85 kg a.s./m³ wood composite instead of 2.6 kg a.s./m³ wood composite. The additional coating which is proposed for use class 3 is not considered in human exposure assessment.

Primary exposure: Application of the biocidal product (industrial use)

Scenario: Preparation of preservative/resin mixture, treatment process; industrial use only

Inhalation exposure is calculated based on saturated concentration in air, a temperature of 423K, an inhalation rate of 1.25 m³/h, a shift of 10 hours and an adult of 60 kg (tier 1) as well as ventilation (reduction to 1 % of the saturation concentration) (tier 2):

Inhalation exposure, tier 1: $< 1.2 \times 10^{-3}$ mg a.s./kg bw/day (**unchanged compared to CAR**)
Inhalation exposure, tier 2: $< 1.2 \times 10^{-5}$ mg a.s./kg bw/day (**unchanged compared to CAR**)

Dermal exposure is not expected. For a realistic worst case consideration the dermal exposure during manual filling and loading as well as direct contact of workers with treated panels is considered.

Dermal exposure during filling and loading is calculated based on model 7, Filling and loading, TNsG on human exposure 2002; exposure of 1.38 mg b.p./min; exposure duration of 5 min; adult of 60 kg; 8% dermal absorption; (tier 1) **PPE (gloves) 10% penetration (changed compared to CAR where 12% were assumed)** (tier 2):
Dermal exposure, tier 1: 2.8×10^{-3} mg a.s./kg bw/day (**unchanged compared to CAR**)
Dermal exposure, tier 2: 2.8×10^{-4} mg a.s./kg bw/day (**changed compared to CAR**)

Dermal exposure due to direct contact of workers with treated panels is estimated based on the scenario described in “Secondary exposure: Dermal exposure of adult during processing of treated wood composites” (tier 1), respectively additional measured data (tier 3), see chapter Additional data submitted for product authorization:
Dermal exposure, tier 1: 3.2×10^{-2} mg a.s./kg bw/day (**changed compared to CAR**)
Dermal exposure, tier 3: 1.2×10^{-4} mg a.s./kg bw/day (**additional measured data)**

Overall dermal exposure, tier 1: 3.5×10^{-2} mg a.s./kg bw/day (**changed compared to CAR**)
Overall dermal exposure, tier 2&3: 4×10^{-4} mg a.s./kg bw/day (**changed compared to CAR**)

Combined exposure: Application of the biocidal product (industrial use)

Exposure (inhalative and dermal, tier 1): 3.6×10^{-2} mg a.s./kg bw/day
Exposure (inhalative and dermal, tier 2&3): 4.1×10^{-4} mg a.s./kg bw/day

Secondary exposure, short term/long term: Inhalation of dust by adult during sanding/processing of treated wood composites

A wood composite board is sanded by an adult person without protective equipment.
Inhalation exposure is calculated based on **2.85 mg a.s./cm³ particle board (changed compared to CAR where 2.6 mg a.s./cm³ particle board were assumed)** (all of the a.s. is in the outer 1 cm layer), a dust concentration in air of 5 mg/m³, a wood density of 680 mg/cm³, inhalation at a rate of 1.25 m³/hour, exposure duration of 1 hour, and an adult of 60 kg:

Inhalation exposure, tier 1: 4.4×10^{-4} mg a.s./kg bw/day (**changed compared to CAR**)

Secondary exposure, short term/long term: Dermal exposure of adult during processing of treated wood composites

A wood composite board is sanded by an adult person without protective equipment.
Dermal exposure is calculated based on **0.285 mg a.s./cm^2 wood composite (changed compared to CAR where 0.26 mg a.s./cm^2 wood composite were assumed)** (all of the a.s. is in the outer 1 cm layer, exposure is to the outer 1mm layer), a hand surface area of 420 cm², a contamination of 20% of the hand surface, and an adult of 60 kg as well as 8% dermal absorption (tier 1), respectively additional measured data (tier 3), see chapter Additional data submitted for product authorization:

Dermal exposure, tier 1: 3.2×10^{-2} mg a.s./kg bw/day (**changed compared to CAR**)
Dermal exposure, tier 3: 1.2×10^{-4} mg a.s./kg bw/day (**additional measured data)**

Combined exposure: adult is sanding wood:

Exposure (inhalative and dermal, tier 1): 3.2×10^{-2} mg a.s./kg bw/day
Exposure (inhalative and dermal, tier 1&3): 5.6×10^{-4} mg a.s./kg bw/day

Secondary exposure, short term: Oral ingestion by infant chewing wood composites chips

An infant chews a wood composite chip of the size 4 x 4 x 1 cm.

Oral exposure is calculated based on **2.85 mg a.s./cm³ particle board (changed compared to CAR where 2.6 mg a.s./cm³ particle board were assumed)** (all of the a.s. is in the outer 1 cm layer), 100% extraction, and a body weight of 10 kg (tier 1) as well as 10% extraction (tier 2):

Oral exposure, tier 1: 4.6 mg a.s./kg bw/day (**changed compared to CAR**)
Oral exposure, tier 2: 4.6×10^{-1} mg a.s./kg bw/day (**changed compared to CAR**)

(See chapter 2.7: This scenario results in an unacceptable risk, however, the use of K-HDO treated wood composites is restricted to applications where biocidal treatment is unavoidable, e.g. construction, but definitely excludes indoor applications allowing direct human contact.)

Secondary exposure, long term: Inhalation by adult exposed to volatilized residues indoors

Inhalation exposure is calculated based on saturated concentration in air, a temperature of 298K, an inhalation rate of 1.25 m³/h, a residence time of 18 hours and an adult of 60 kg (tier 1) as well as ventilation (reduction to 1% of the saturation concentration) (tier 2):

Inhalation exposure, tier 1: < 3.0 x 10^{-3} mg a.s./kg bw/day (**unchanged compared to CAR**)
Inhalation exposure, tier 2: < 3.0 x 10^{-5} mg a.s./kg bw/day (**unchanged compared to CAR**)

Secondary exposure, long term: Inhalation by infant exposed to volatilized residues indoors

Inhalation exposure is calculated based on saturated concentration in air, a temperature of 298K, an inhalation rate of 1.25 m³/h, a residence time of 18 hours and an adult of 10 kg (tier 1) as well as ventilation (reduction to 1% of the saturation concentration) (tier 2):

Inhalation exposure, tier 1: < 3.2 x 10^{-3} mg a.s./kg bw/day (**unchanged compared to CAR**)
Inhalation exposure, tier 2: < 3.2 x 10^{-5} mg a.s./kg bw/day (**unchanged compared to CAR**)

Additional data submitted for product authorisation:

For product authorization, study B 6.6/02 (“Surface sampling and analysis for residues of K-HDO from Xyligen treated particle and ply wood boards by the wipe test”) was submitted, performed according to OPPTS 875.2300 (draft) and OPPTS 875.2400.

A total of 28 wood samples (12 particle boards treated with Xyligen 25 F, content of K-HDO: 2.2 kg/m³; 8 particle boards treated with Xyligen 30 F, two of these boards coated on the back side, coating not specified, content of K-HDO: 1.95 kg/m³; 8 plywood boards treated with Xyligen 25 F, content of K-HDO: 2.6 kg/m³) was wiped with wet and dry tissues. The area (between 550 and 630 cm²) was only wiped once, with a pressure of ca. 1200Pa (information in the study report: weight of wiping device is 607.7 g; area of wiping device is 50 cm²; no information, of additional pressure is applied)

The tissues were extracted with 75 mL eluent (55 parts 0.05 m KH_2PO_4, 45 parts methanol) and analysed with HPLC-UV. For 22 boards, the analyte concentration was below the LOQ (14 µg/tissue, corresponding to ca. 0.025 µg / cm² board). For 6 boards, concentrations between 0.038 and 0.053 µg / cm² board could be detected (uncoated boards, wet wipes).

OPPTS 875.2300 (draft) quotes:

“Residues that can be transferred from the treated surface as a result of contact can be measured using wipe sampling. This technique uses moistened cotton gauze pads to sample a standardized area. […]This is a relatively simple technique that can be conducted on a variety of surfaces.

The number of times that the surface should be wiped is not consistent. A weight may be attached to the sampling pad to apply uniform pressure. Research has shown that when two wipes are done (sampled area wiped twice using two pads in two directions and applying maximum pressure by the hand), the second wipe can yield almost as much residue as the first wipe (Naffziger et al., 1985). To minimize variability in results, certain factors should be considered (standardizing the sampling material, standardizing the area to be wiped, outlining the boundaries of the surface to be wiped with tape or a template, wiping the sample area once with firm even pressure, collecting samples in triplicate, checking the moisture content of the wipe). As with the previous techniques, samples should be collected at sufficient intervals to establish a dissipation curve. In general, wipe samplers should only be used on hard surfaces (i.e., not carpeting).”

Study B 6.6/02 can only be assigned a reliability factor (Klimisch score) of 2, as the study was not performed according to GLP, as it is unknown if the applied pressure is maximum pressure by the hand, and as samples were not collected at sufficient intervals to establish a dissipation curve.

As the second wipe can yield almost as much residue as the first wipe, as a realistic worst case and in absence of measured data, 20 wipes yielding in max. residues are assumed, resulting in 20 x 0.053µg/cm² = 1.06 x 10^{-3} mg/cm².
Following the logics of the model “Dermal exposure of adult during processing of treated wood composites”, assuming a hand surface area of 420 cm², a contamination of 20% of the hand surface, and an adult of 60 kg as well as 8% dermal absorption, this results in the following dermal exposure:

Dermal exposure, tier 3 (measured data): 1.2 x 10^{-4} mg a.s./kg bw/day

2.6.3 Assessment of exposure to the environment

According to the Intended use the biocidal product Xyligen 30 F is used in Use Class 2 and 3.
In the Competent authority report accompanying the Annex I inclusion, for Use Class 2 environmental exposure during manufacturing, industrial application of the biocidal product Xyligen 30 F and service life of treated wood composites to the aquatic and terrestrial environment is assumed to be negligible.

Therefore in the following only environmental exposure for UC 3 is considered.

According to the Intendes Use Xyligen 30 F is used for scaffolding boards only with an additional top coating which should prevent any leaching (study B 7.1/02).

Additional data submitted for product authorisation:
For product authorisation study B 7.1/02[1], was submitted performed according to CEN TR 15119.
The experimental laboratory study was performed to determine the leaching behavior of the active ingredient K-HDO from treated and top coated plywood boards in UC3.
The plywood boards were industrially manufactured. For this study freshly manufactured plywood board (immediately upon completion) and a return after its completed service life time of approx. 9 years were used for measurements. The content of Xyligen 30 F in both plywood boards is 11 kg/m³.

Two samples of the test specimens (Plywood boards Type BFU 100G acc. to DIN 68705-3:1981-12: 150x50x10mm with a top coating according to DIN 53 799) were placed in one test container to get an immersed wood surface of 0.036m^2. A dipping time of 2x1 hour per dipping event was used (8:00 and 14:00). Two replicates and one setup with untreated controls were prepared. The water was not changed between the daily immersion events.
The retention of the plywood boards has been analytically verified. The retention of the "new" manufactured plywood board amounts to 11.1 kg/m³. The retention of the "old" plywood board after a service time of approx. 9 years was 10.9 kg/m³. The limit of detection is 0.05 mg/L K-HDO.
Both retentions correlate well with the required retention of Xyligen 30 F treated plywood boards.

In all water samples no contamination of K-HDO could be detected. Therefore the emission rate of K-HDO from freshly treated (two weeks) and old coated plywood boards (approx. 9 years) is below the LOD of 0.05 mg/L.

Therefore the potential emission from scaffolding boards with top coating to the environment is considered negligible because:

- UC3 is limited to plywood boards for scaffolding only
- top coating is applied during industrial application process only
- scaffolding boards cannot be used without top coating
- damaged boards will be disposed for safety reasons
- environmental exposure of scaffolding boards is not comparable to other UC3 scenarios (shorter time period/different locations).

However, in addition for a realistic worst case consideration, the leaching rate was calculated by the limit of detection of the used analytical method. This approach was also discussed and agreed by the TM I 2011 (Agenda item ”5b. Topcoating PT 08” of the environmental session).

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[1] Hettler, W, 2008: Leaching behavior of Xyligen 30 F treated plywood boards exposed in UC 3, Dr. Wolman GmbH, Sinzheim. Germany.

In general it can be assumed that scaffolding boards are removed after a short time period. According to the applicant a time period of 30 days is considered as a realistic time frame. Therefore the cumulated emissions after the first 30 days are used for the calculation of the relevant realistic worst case PEC values.

Based on the Leaching test described above, the calculated emission (22 days) is given by:

Daily emission = LOD x water volume x number of measurement / surface / days

= 0.05 mg/L x 0.883 L x 7 / 0.036 m² / 22 = 0.3902 mg/m² *d

For a time period of 30 days the realistic worst case emission is:
0.3902 mg/m²*d x 30 d = 11.7 mg/m².

The realistic worst case emission is used for calculation of PEC values.
No Emission Scenario Document is available, which addresses the application of biocidal products onto scaffolding boards. Therefore the following exposure assessment should be seen as possible representative realistic worst case scenario for scaffolding boards.

Although a house scenario exists in the OECD ESD for PT8, this house seems not to be the best example for a house surrounded by scaffolding boards since it is only 2.5 m high.
Therefore in the following a one-family house in the countryside[2] and a multi-storey building in the city[3] are considered to be surrounded with scaffolding boards.

- A) House in the countryside[2]:

  Length: 10.7 m
  Width: 8.7 m
  Height: 8.3 m

- B) Multi-storey building in the city[3]

  Storefront facade:

Length Spittelauer Lände 5:	28.32 m (yellow line)
Length Ingen Housz Gasse 6:	32.25 m (yellow line)
Height:	25.31 m

  Patio (only 3 sides, see red lines):
  18.5 m, 17 m and 17.6 m

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[2] http://www.holzforschung.at/hfa-forschungshaus.html

[3] Umweltbundesamt GmbH Building, Spittelauer Lände 5, as an example, see photo from Google Maps and photo on UBA-website http://www.umweltbundesamt.at/ueberuns/kontakt/

Source: http://maps.google.com/maps?hl=en&rls=com.microsoft:en-gb:IE-ContextMenu&q=spittelauerl%C3%A4nde+5&bav=on.2,or.r_gc.r_pw.&wrapid=tlif130087154245910&um=1&ie=UTF-8&sa=N&tab=wl

For both scenarios (house in the countryside (A), multi-storey building in the city (B)) two approaches are chosen in the following:

1. A reverse calculation was conducted to estimate how many scaffolding boards (in m^2) can be used simultaneously without causing any risk (PEC/PNEC<1) to the relevant environmental compartment(s).
2. In comparison a realistic scenario of scaffolding boards in m^2 for one-family house in the countryside and for the multi-storey building in the city based on the information submitted by the applicant is presented.

The PEC values are calculated for the following scnearios:

Scenario	**Reverse calculation**	**Realistic calculation**
house in the countryside	• direct release to soil (page 24)	• direct release to soil (page 25)
multi-storey building in the city	• direct release to stp (page 26) • direct release to surface water (page 48)	

A) House in the countryside (one-family house): direct emissions to soil adjacent to house and porewater

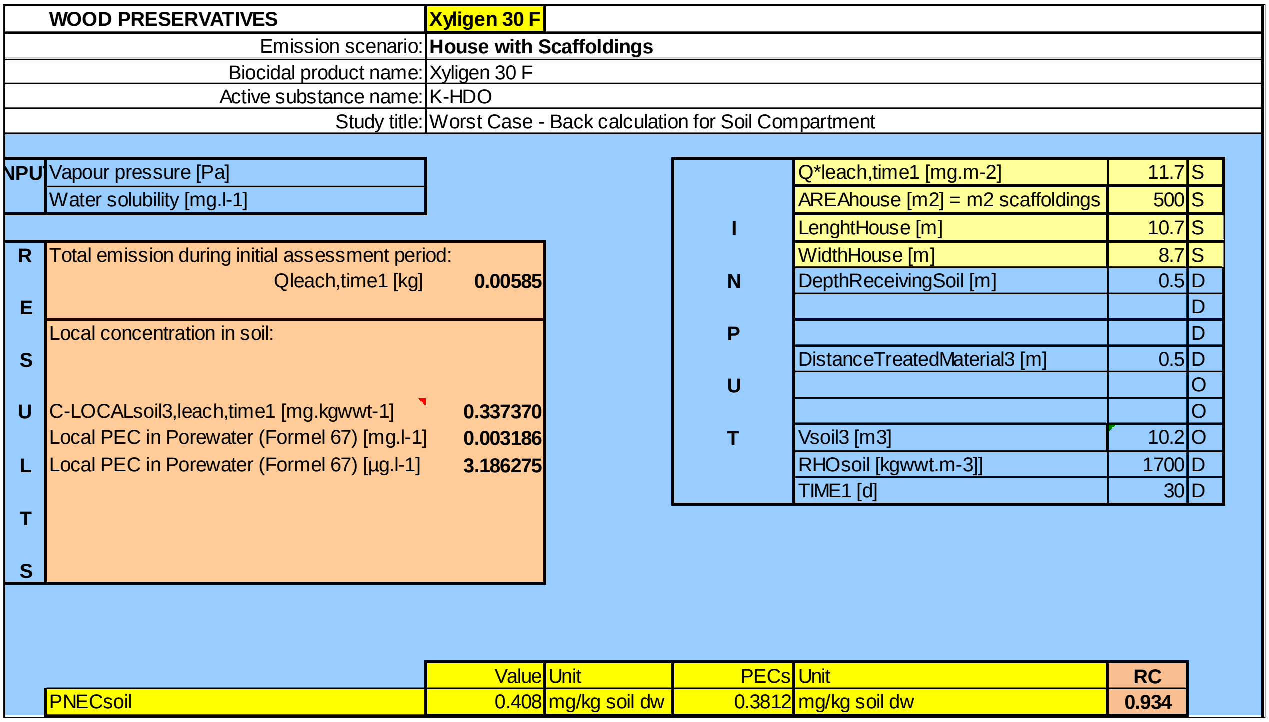
Length: 10.7 m
Width: 8.7 m
Height: 8.3 m

1. Reverse calculation:

Question: How many scaffolding boards are necessary to cause a risk to the soil compartment based on $PNEC_{soil}$ = 0.408 mg/kg soil dw?

Answer: 500 m^2 boards result in a PEC/PNEC ratio of 0.9. It should be noted that this calculation should only demonstrate how many scaffolding boards are necessary to cause a risk to the soil compartment. The realistic scenario is presented below.

Table 2.6.3-1: House in the countryside-Reverse calculation[1]



WOOD PRESERVATIVES	**Xyligen 30 F**
Emission scenario:	**House with Scaffoldings**
Biocidal product name:	Xyligen 30 F
Active substance name:	K-HDO
Study title:	Worst Case - Back calculation for Soil Compartment

NPU	Vapour pressure [Pa]	
	Water solubility [mg.l-1]	

INPUT	Q*leach,time1 [mg.m-2]	11.7	S
	AREAhouse [m2] = m2 scaffoldings	500	S
	LenghtHouse [m]	10.7	S
	WidthHouse [m]	8.7	S
	DepthReceivingSoil [m]	0.5	D
			D
			D
	DistanceTreatedMaterial3 [m]	0.5	D
			O
			O
	Vsoil3 [m3]	10.2	O
	RHOsoil [kgwwt.m-3]]	1700	D
	TIME1 [d]	30	D

RESULTS	Total emission during initial assessment period: Qleach,time1 [kg]	**0.00585**
	Local concentration in soil:	
	C-LOCALsoil3,leach,time1 [mg.kgwwt-1]	**0.337370**
	Local PEC in Porewater (Formel 67) [mg.l-1]	**0.003186**
	Local PEC in Porewater (Formel 67) [µg.l-1]	**3.186275**

	Value	Unit	PECs	Unit	**RC**
PNECsoil	0.408	mg/kg soil dw	0.3812	mg/kg soil dw	**0.934**

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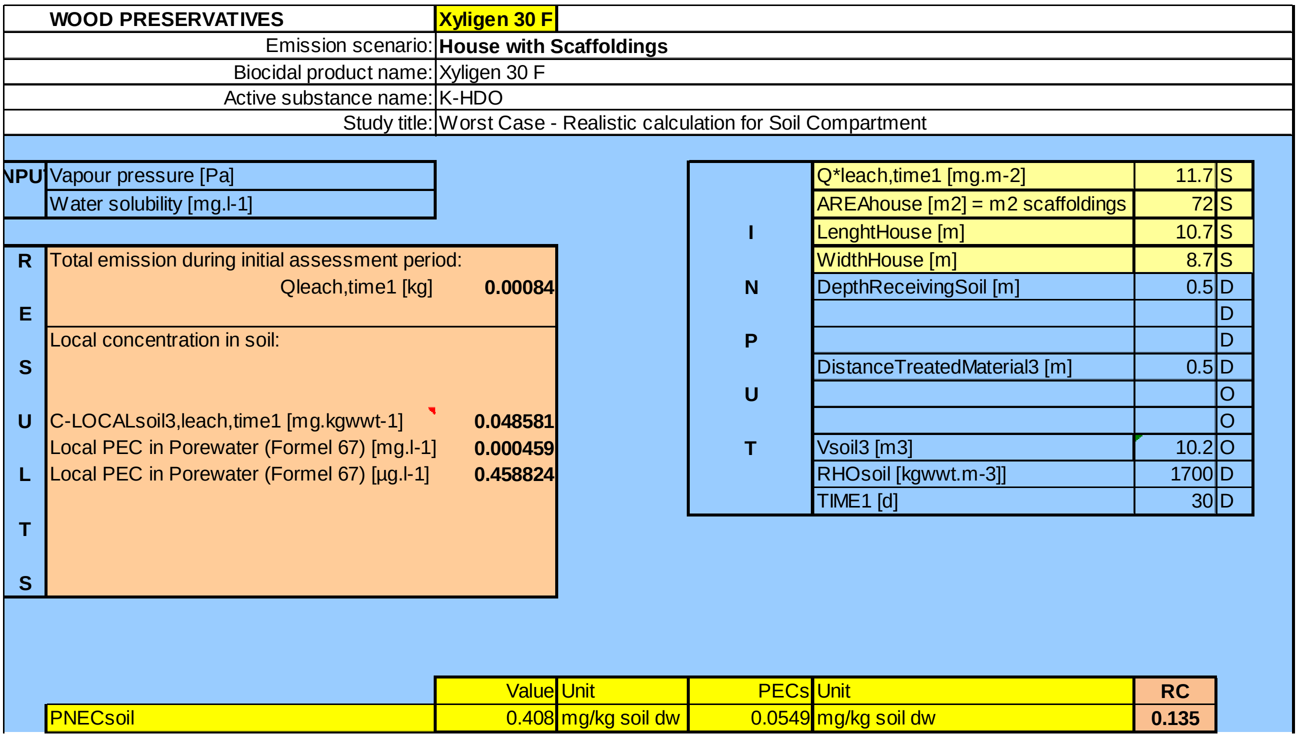
[1] S: set; D: default; O: output;

2. Realistic Scenario

According to the applicant for the length of 10.7 m, 4 standard sized boards are necessary. For the width of 8.7 m, 4 standard sized boards are necessary too. For 1 stage of the scaffold a total of 16 boards are necessary. It is assumed that each stage of scaffolds should have a height of approx. 2-2.2 m. Therefore for the requested house with a height of 8.3 m, 3 scaffold stages are required.
In this case the total scaffolding board surface is (16 x 3 x 2.5 x 0.6 m) = 72 m².

Table 2.6.3-2: House in the countryside – Realistic Scenario[1]



WOOD PRESERVATIVES	Xyligen 30 F
Emission scenario:	**House with Scaffoldings**
Biocidal product name:	Xyligen 30 F
Active substance name:	K-HDO
Study title:	Worst Case - Realistic calculation for Soil Compartment

NPU	
	Vapour pressure [Pa]
	Water solubility [mg.l-1]

R E S U L T S		
	Total emission during initial assessment period:	
	Qleach,time1 [kg]	**0.00084**
	Local concentration in soil:	
	C-LOCALsoil3,leach,time1 [mg.kgwwt-1]	**0.048581**
	Local PEC in Porewater (Formel 67) [mg.l-1]	**0.000459**
	Local PEC in Porewater (Formel 67) [µg.l-1]	**0.458824**

I N P U T			
	Q*leach,time1 [mg.m-2]	11.7	S
	AREAhouse [m2] = m2 scaffoldings	72	S
	LenghtHouse [m]	10.7	S
	WidthHouse [m]	8.7	S
	DepthReceivingSoil [m]	0.5	D
			D
			D
	DistanceTreatedMaterial3 [m]	0.5	D
			O
			O
	Vsoil3 [m3]	10.2	O
	RHOsoil [kgwwt.m-3]]	1700	D
	TIME1 [d]	30	D

	Value	Unit	PECs	Unit	RC
PNECsoil	0.408	mg/kg soil dw	0.0549	mg/kg soil dw	**0.135**

[1] S: set; D: default; O: output;

72 m^2 scaffolding boards result in a PEC/PNEC ratio of 0.135 for the soil compartment. The PEC Porewater for K-HDO is above the parametic value of 0.1µg/L according to Directive 98/83/EC. However it should be noted that the PECporewater is a realistic worst case assumption, neglecting transformation and dilution in deeper soil layers.

See equation for deriving the concentration in the pore water below:

$$PEClocal\ soil, porw\ (mg/L) = \frac{PEClocalsoil\ \times RHOsoil}{Ksoil - water\ x\ 1000}\ \ TGD\ (67)$$

Based on the reasons discussed above, this calculated, but worst case exceedance (max 0.46 µg/L) is still acceptable.

B) Multi-storey building in the city:

In the following a total scaffolding board surface of 10,000 m^2 is used as input parameter for calculating the

- direct emissions to STP (indirect via surface water, sediment and soil and porewater) and
- direct emissions to surface water (a realistic worst case assumption of bypassing the STP)

1. Reverse calculation:

Question: How many scaffolding boards are necessary to cause a risk for the following compartments?

- **STP:** based on PNECstp of 0.09 mg/l
- **Surface water:** based on PNEC water of 9.40 x10^{-3} mg/l
- **Sediment:** equilibrium partitioning theory derived from the PNEC$_{water}$
- **Soil:** based on PNEC$_{soil}$ of 0.408 mg/kg soil dw

Answer: The resulting PEC/PNEC ratios are far below < 1 for a total scaffolding board surface of 10,000 m^2. (See table 2.6.3-3 and table 2.6.3-4). Taking into account the realistic scenario below, which assumes a total surface of about 775.5 m^2 for one multi-storey building (details below) this are about 10 to 13 multi-storey buildings/STP.

- direct emissions to STP (indirect via surface water, sediment and soil and porewater)

Table 2.6.3-3: EUSES Output file: Multi-storey building in the city, direct release to STP
(abbreviations: S: set; D: default; O: output; I: input)

Section/parameter		**Actual value**	**Unit**	**Status**
STUDY				
STUDY IDENTIFICATION				
Study name		K-HDO		S
Study description		Xyligen		S
DEFAULTS				
DEFAULT IDENTIFICATION				
General name		Standard Euses 2.1		D
Description		According to TGDs		D
CHARACTERISTICS OF COMPARTMENTS				
GENERAL				
Density of solid phase		2.5	[kg.l-1]	D
Density of water phase		1	[kg.l-1]	D
Density of air phase		1.30E-03	[kg.l-1]	D
Environmental temperature		12	[oC]	D
Standard temperature for Vp and Sol		25	[oC]	D
Temperature correction method		Temperature correction for local distribution		D

Constant of Junge equation		0.01	[Pa.m]	D
Surface area of aerosol particles		0.01	[m2.m-3]	D
Gas constant (8.314)		8.314	[Pa.m3.mol-1.K-1]	D
SUSPENDED MATTER				
Volume fraction solids in suspended matter		0.1	[m3.m-3]	D
Volume fraction water in suspended matter		0.9	[m3.m-3]	D
Weight fraction of organic carbon in suspended matter		0.1	[kg.kg-1]	D
Bulk density of suspended matter		1.15E+03	[kgwwt.m-3]	O
Conversion factor wet-dry suspened matter		4.6	[kgwwt.kgdwt-1]	O
SEDIMENT				
Volume fraction solids in sediment		0.2	[m3.m-3]	D
Volume fraction water in sediment		0.8	[m3.m-3]	D
Weight fraction of organic carbon in sediment		0.05	[kg.kg-1]	D
SOIL				
Volume fraction solids in soil		0.6	[m3.m-3]	D
Volume fraction water in soil		0.2	[m3.m-3]	D
Volume fraction air in soil		0.2	[m3.m-3]	D
Weight fraction of organic carbon in soil		0.02	[kg.kg-1]	D
Weight fraction of organic matter in soil		0.034	[kg.kg-1]	O
Bulk density of soil		1.70E+03	[kgwwt.m-3]	O
Conversion factor wet-dry soil		1.13	[kgwwt.kgdwt-1]	O
STP SLUDGE				
Fraction of organic carbon in raw sewage sludge		0.3	[kg.kg-1]	D
Fraction of organic carbon in settled sewage sludge		0.3	[kg.kg-1]	D
Fraction of organic carbon in activated sewage sludge		0.37	[kg.kg-1]	D
Fraction of organic carbon in effluent sewage sludge		0.37	[kg.kg-1]	D
DEGRADATION AND TRANSFORMATION RATES				
Rate constant for abiotic degradation in STP		1.00E+40	[d] (DT50)	D
Rate constant for abiotic degradation in bulk sediment		0	[d-1] (12[oC])	D
Rate constant for anaerobic		0	[d-1] (12[oC])	D

biodegradation in sediment			
Fraction of sediment compartment that is aerated	0.1	[m3.m-3]	D
Concentration of OH-radicals in atmosphere	5.00E+05	[molec.cm-3]	D
Rate constant for abiotic degradation in bulk soil	0	[d-1] (12[oC])	D
RELEASE ESTIMATION			
Fraction of EU production volume for region	100	[%]	D
Fraction of EU tonnage for region (private use)	10	[%]	D
Fraction connected to sewer systems	80	[%]	D
SEWAGE TREATMENT			
GENERAL			
Number of inhabitants feeding one STP	1.00E+04	[eq]	D
Sewage flow	200	[l.eq-1.d-1]	D
Effluent discharge rate of local STP	2.00E+06	[l.d-1]	O
Temperature correction for STP degradation	No		D
Temperature of air above aeration tank	15	[oC]	D
Temperature of water in aeration tank	15	[oC]	D
Height of air column above STP	10	[m]	D
Number of inhabitants of region	2.00E+07	[eq]	D
Number of inhabitants of continental system	3.50E+08	[eq]	O
Windspeed in the system	3	[m.s-1]	D
RAW SEWAGE			
Mass of O2 binding material per person per day	54	[g.eq-1.d-1]	D
Dry weight solids produced per person per day	0.09	[kg.eq-1.d-1]	D
Density solids in raw sewage	1.5	[kg.l-1]	D
Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D
PRIMARY SETTLER			
Depth of primary settler	4	[m]	D
Hydraulic retention time of primary settler	2	[hr]	D
Density suspended and settled solids in primary settler	1.5	[kg.l-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D

ACTIVATED SLUDGE TANK				
Depth of aeration tank		3	[m]	D
Density solids of activated sludge		1.3	[kg.l-1]	D
Concentration solids of activated sludge		4	[kg.m-3]	D
Steady state O2 concentration in activated sludge		2.00E-03	[kg.m-3]	D
Mode of aeration		Surface		D
Aeration rate of bubble aeration		1.31E-05	[m3.s-1.eq-1]	D
Fraction of organic carbon in activated sewage sludge		0.37	[kg.kg-1]	D
Sludge loading rate		0.15	[kg.kg-1.d-1]	D
Hydraulic retention time in aerator (9-box STP)		6.9	[hr]	O
Hydraulic retention time in aerator (6-box STP)		10.8	[hr]	O
Sludge retention time of aeration tank		9.2	[d]	O
SOLIDS-LIQUIDS SEPARATOR				
Depth of solids-liquid separator		3	[m]	D
Density suspended and settled solids in solids-liquid separator		1.3	[kg.l-1]	D
Concentration solids in effluent		30	[mg.l-1]	D
Hydraulic retention time of solids-liquid separator		6	[hr]	D
Fraction of organic carbon in effluent sewage sludge		0.37	[kg.kg-1]	D
LOCAL DISTRIBUTION				
AIR AND SURFACE WATER				
Concentration in air at source strength 1 [kg.d-1]		2.78E-04	[mg.m-3]	D
Standard deposition flux of aerosol-bound compounds		0.01	[mg.m-2.d-1]	D
Standard deposition flux of gaseous compounds		5.00E-04	[mg.m-2.d-1]	O
Suspended solids concentration in STP effluent water		15	[mg.l-1]	D
Dilution factor (rivers)		10	[-]	D
Flow rate of the river		1.80E+04	[m3.d-1]	D
Calculate dilution from river flow rate		No		S
Dilution factor (coastal areas)		100	[-]	D
SOIL				

Mixing depth of grassland soil		0.1	[m]	D
Dry sludge application rate on agricultural soil		5.00E+03	[kg.ha-1.yr-1]	D
Dry sludge application rate on grassland		1000	[kg.ha-1.yr-1]	D
Averaging time soil (for terrestrial ecosystem)		30	[d]	D
Averaging time agricultural soil		180	[d]	D
Averaging time grassland		180	[d]	D
PMTC, air side of air-soil interface		1.05E-03	[m.s-1]	O
Soil-air PMTC (air-soil interface)		5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)		5.56E-10	[m.s-1]	D
Mixing depth agricultural soil		0.2	[m]	D
Fraction of rain water infiltrating soil		0.25	[-]	D
Average annual precipitation		700	[mm.yr-1]	D
REGIONAL AND CONTINENTAL DISTRIBUTION				
CONFIGURATION				
Fraction of direct regional emissions to seawater		1	[%]	D
Fraction of direct continental emissions to seawater		0	[%]	D
Fraction of regional STP effluent to seawater		0	[%]	D
Fraction of continental STP effluent to seawater		0	[%]	D
Fraction of flow from continental rivers to regional rivers		0.034	[-]	D
Fraction of flow from continental rivers to regional sea		0	[-]	D
Fraction of flow from continental rivers to continental sea		0.966	[-]	O
Number of inhabitants of region		2.00E+07	[eq]	D
Number of inhabitants in the EU		3.70E+08	[eq]	D
Number of inhabitants of continental system		3.50E+08	[eq]	O
AREAS				
REGIONAL				
Area (land+rivers) of regional system		4.00E+04	[km2]	D
Area fraction of freshwater, region (excl. sea)		0.03	[-]	D
Area fraction of natural soil, region (excl. sea)		0.27	[-]	D
Area fraction of agricultural soil, region		0.6	[-]	D

(excl. sea)				
Area fraction of industrial/urban soil, region (excl. sea)		0.1	[-]	D
Length of regional seawater		40	[km]	D
Width of regional seawater		10	[km]	D
Area of regional seawater		400	[km2]	O
Area (land+rivers+sea) of regional system		4.04E+04	[km2]	O
Area fraction of freshwater, region (total)		0.0297	[-]	O
Area fraction of seawater, region (total)		9.90E-03	[-]	O
Area fraction of natural soil, region (total)		0.267	[-]	O
Area fraction of agricultural soil, region (total)		0.594	[-]	O
Area fraction of industrial/urban soil, region (total)		0.099	[-]	O
CONTINENTAL				
Total area of EU (continent+region, incl. sea)		7.04E+06	[km2]	D
Area (land+rivers+sea) of continental system		7.00E+06	[km2]	O
Area (land+rivers) of continental system		3.50E+06	[km2]	O
Area fraction of freshwater, continent (excl. sea)		0.03	[-]	D
Area fraction of natural soil, continent (excl. sea)		0.27	[-]	D
Area fraction of agricultural soil, continent (excl. sea)		0.6	[-]	D
Area fraction of industrial/urban soil, continent (excl. sea)		0.1	[-]	D
Area fraction of freshwater, continent (total)		0.015	[-]	O
Area fraction of seawater, continent (total)		0.5	[-]	D
Area fraction of natural soil, continent (total)		0.135	[-]	O
Area fraction of agricultural soil, continent (total)		0.3	[-]	O
Area fraction of industrial/urban soil, continent (total)		0.05	[-]	O
MODERATE				
Area of moderate system (incl.continent,region)		8.50E+07	[km2]	D
Area of moderate system (excl.continent, region)		7.80E+07	[km2]	O
Area fraction of water, moderate system		0.5	[-]	D
ARCTIC				

Area of arctic system		4.25E+07	[km2]	D
Area fraction of water, arctic system		0.6	[-]	D
TROPIC				
Area of tropic system		1.28E+08	[km2]	D
Area fraction of water, tropic system		0.7	[-]	D
TEMPERATURE				
Environmental temperature, regional scale		12	[oC]	D
Environmental temperature, continental scale		12	[oC]	D
Environmental temperature, moderate scale		12	[oC]	D
Environmental temperature, arctic scale		-10	[oC]	D
Environmental temperature, tropic scale		25	[oC]	D
Enthalpy of vaporisation		50	[kJ.mol-1]	D
Enthalpy of solution		10	[kJ.mol-1]	D
MASS TRANSFER				
Air-film PMTC (air-water interface)		4.14E-03	[m.s-1]	O
Water-film PMTC (air-water interface)		4.92E-06	[m.s-1]	O
PMTC, air side of air-soil interface		1.05E-03	[m.s-1]	O
PMTC, soil side of air-soil interface		4.34E-11	[m.s-1]	O
Soil-air PMTC (air-soil interface)		5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)		5.56E-10	[m.s-1]	D
Water-film PMTC (sediment-water interface)		2.78E-06	[m.s-1]	D
Pore water PMTC (sediment-water interface)		2.78E-08	[m.s-1]	D
AIR				
GENERAL				
Atmospheric mixing height		1000	[m]	D
Windspeed in the system		3	[m.s-1]	D
Aerosol deposition velocity		1.00E-03	[m.s-1]	D
Aerosol collection efficiency		2.00E+05	[-]	D
RAIN				
Average precipitation, regional system		700	[mm.yr-1]	D

Average precipitation, continental system		700	[mm.yr-1]	D
Average precipitation, moderate system		700	[mm.yr-1]	D
Average precipitation, arctic system		250	[mm.yr-1]	D
Average precipitation, tropic system		1.30E+03	[mm.yr-1]	D
RESIDENCE TIMES				
Residence time of air, regional		0.687	[d]	O
Residence time of air, continental		9.05	[d]	O
Residence time of air, moderate		30.2	[d]	O
Residence time of air, arctic		22.3	[d]	O
Residence time of air, tropic		38.6	[d]	O
WATER				
DEPTH				
Water depth of freshwater, regional system		3	[m]	D
Water depth of seawater, regional system		10	[m]	D
Water depth of freshwater, continental system		3	[m]	D
Water depth of seawater, continental system		200	[m]	D
Water depth, moderate system		1000	[m]	D
Water depth, arctic system		1000	[m]	D
Water depth, tropic system		1000	[m]	D
SUSPENDED SOLIDS				
Suspended solids conc. freshwater, regional		15	[mg.l-1]	D
Suspended solids conc. seawater, regional		5	[mg.l-1]	D
Suspended solids conc. freshwater, continental		15	[mg.l-1]	D
Suspended solids conc. seawater, continental		5	[mg.l-1]	D
Suspended solids conc. seawater, moderate		5	[mg.l-1]	D
Suspended solids conc. seawater, arctic		5	[mg.l-1]	D
Suspended solids conc. seawater, tropic		5	[mg.l-1]	D
Concentration solids in effluent, regional		30	[mg.l-1]	D
Concentration solids in effluent, continental		30	[mg.l-1]	D

Concentration biota		1	[mgwwt.l-1]	D
RESIDENCE TIMES				
Residence time of freshwater, regional		43.3	[d]	O
Residence time of seawater, regional		4.64	[d]	O
Residence time of freshwater, continental		172	[d]	O
Residence time of seawater, continental		365	[d]	O
Residence time of water, moderate		2.69E+03	[d]	O
Residence time of water, arctic		5.84E+03	[d]	O
Residence time of water, tropic		1.09E+04	[d]	O
SEDIMENT				
DEPTH				
Sediment mixing depth		0.03	[m]	D
SUSPENDED SOLIDS				
(Biogenic) prod. susp. solids in freshwater, reg		10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in seawater, reg		10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in freshwater, cont		10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in seawater, cont		5	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, moderate		1	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, arctic		1	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, tropic		1	[g.m-2.yr-1]	D
SEDIMENTATION RATES				
Settling velocity of suspended solids		2.5	[m.d-1]	D
Net sedimentation rate, freshwater, regional		2.8	[mm.yr-1]	O
Net sedimentation rate, seawater, regional		1.53	[mm.yr-1]	O
Net sedimentation rate, freshwater, continental		2.75	[mm.yr-1]	O
Net sedimentation rate, seawater, continental		6.69E-03	[mm.yr-1]	O
Net sedimentation rate, moderate		2.80E-03	[mm.yr-1]	O
Net sedimentation rate, arctic		2.00E-03	[mm.yr-1]	O
Net sedimentation rate, tropic		2.00E-03	[mm.yr-1]	O

SOIL				
GENERAL				
Fraction of rain water infiltrating soil		0.25	[-]	D
Fraction of rain water running off soil		0.25	[-]	D
DEPTH				
Chemical-dependent soil depth		No		D
Mixing depth natural soil		0.05	[m]	D
Mixing depth agricultural soil		0.2	[m]	D
Mixing depth industrial/urban soil		0.05	[m]	D
Mixing depth of soil, moderate system		0.05	[m]	D
Mixing depth of soil, arctic system		0.05	[m]	D
Mixing depth of soil, tropic system		0.05	[m]	D
EROSION				
Soil erosion rate, regional system		0.03	[mm.yr-1]	D
Soil erosion rate, continental system		0.03	[mm.yr-1]	D
Soil erosion rate, moderate system		0.03	[mm.yr-1]	D
Soil erosion rate, arctic system		0.03	[mm.yr-1]	D
Soil erosion rate, tropic system		0.03	[mm.yr-1]	D
CHARACTERISTICS OF PLANTS, WORMS AND CATTLE				
PLANTS				
Volume fraction of water in plant tissue		0.65	[m3.m-3]	D
Volume fraction of lipids in plant tissue		0.01	[m3.m-3]	D
Volume fraction of air in plant tissue		0.3	[m3.m-3]	D
Correction for differences between plant lipids and octanol		0.95	[-]	D
Bulk density of plant tissue (wet weight)		0.7	[kg.l-1]	D
Rate constant for metabolism in plants		0	[d-1]	D
Rate constant for photolysis in plants		0	[d-1]	D
Leaf surface area		5	[m2]	D
Conductance		1.00E-03	[m.s-1]	D
Shoot volume		2	[l]	D
Rate constant for dilution by growth		0.035	[d-1]	D
Transpiration stream		1	[l.d-1]	D

WORMS				
Volume fraction of water inside a worm		0.84	[m3.m-3]	D
Volume fraction of lipids inside a worm		0.012	[m3.m-3]	D
Density of earthworms		1	[kgwwt.l-1]	D
Fraction of gut loading in worm		0.1	[kg.kg-1]	D
CATTLE				
Daily intake for cattle of grass (dryweight)		16.9	[kg.d-1]	D
Conversion factor grass from dryweight to wetweight		4	[kg.kg-1]	D
Daily intake of soil (dryweight)		0.41	[kg.d-1]	D
Daily inhalation rate for cattle		122	[m3.d-1]	D
Daily intake of drinking water for cattle		55	[l.d-1]	D
SUBSTANCE				
SUBSTANCE IDENTIFICATION				
General name		K-HDO/ Xyligen		S
Description				D
CAS-No				D
EC-notification no.				D
EINECS no.				D
PHYSICO-CHEMICAL PROPERTIES				
Molecular weight		182.3	[g.mol-1]	S
Melting point		163.1	[oC]	S
Boiling point		??	[oC]	D
Vapour pressure at test temperature		6.00E-06	[Pa]	S
Temperature at which vapour pressure was measured		20	[oC]	S
Vapour pressure at 25 [oC]		8.47E-06	[Pa]	O
Octanol-water partition coefficient		-0.2	[log10]	S
Water solubility at test temperature		4.52E+05	[mg.l-1]	S
Temperature at which solubility was measured		20	[oC]	S
Water solubility at 25 [oC]		4.84E+05	[mg.l-1]	O
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS				
SOLIDS-WATER				
Chemical class for Koc-QSAR		Non-hydrophobics (default QSAR)		S

Organic carbon-water partition coefficient		6.01E+03	[l.kg-1]	S
Solids-water partition coefficient in soil		120	[l.kg-1]	O
Solids-water partition coefficient in sediment		300	[l.kg-1]	O
Solids-water partition coefficient suspended matter		601	[l.kg-1]	O
Solids-water partition coefficient in raw sewage sludge		1.80E+03	[l.kg-1]	O
Solids-water partition coefficient in settled sewage sludge		1.80E+03	[l.kg-1]	O
Solids-water partition coefficient in activated sewage sludge		2.22E+03	[l.kg-1]	O
Solids-water partition coefficient in effluent sewage sludge		2.22E+03	[l.kg-1]	O
Soil-water partition coefficient		180	[m3.m-3]	O
Suspended matter-water partition coefficient		151	[m3.m-3]	O
Sediment-water partition coefficient		151	[m3.m-3]	O
AIR-WATER				
Environmental temperature		12	[oC]	D
Water solubility at environmental temperature		4.03E+05	[mg.l-1]	O
Vapour pressure at environmental temperature		3.37E-06	[Pa]	O
Sub-cooled liquid vapour pressure		1.23E-04	[Pa]	O
Fraction of chemical associated with aerosol particles		0.448	[-]	O
Henry's law constant at 25 [oC]		4.40E-07	[Pa.m3.mol-1]	S
Henry's law constant at enviromental temparature		1.53E-09	[Pa.m3.mol-1]	O
Air-water partitioning coefficient		6.44E-13	[m3.m-3]	O
BIOCONCENTRATION FACTORS				
PREDATOR EXPOSURE				
Bioconcentration factor for earthworms		0.848	[l.kgwwt-1]	O
HUMAN AND PREDATOR EXPOSURE				
Bioconcentration factor for fish		0.134	[l.kgwwt-1]	S
QSAR valid for calculation of BCF-Fish		Yes		O
Biomagnification factor in fish		1	[-]	O
Biomagnification factor in predator		1	[-]	O

HUMAN EXPOSURE			
Partition coefficient between leaves and air	1.02E+12	[m3.m-3]	O
Partition coefficient between plant tissue and water	0.656	[m3.m-3]	O
Transpiration-stream concentration factor	0.157	[-]	O
Bioaccumulation factor for meat	7.94E-07	[d.kg-1]	O
Bioaccumulation factor for milk	7.94E-06	[d.kg-1]	O
Purification factor for surface water	1	[-]	O
DEGRADATION AND TRANSFORMATION RATES			
CHARACTARIZATION			
Characterization of biodegradability	Not biodegradable		S
STP			
Degradation calculation method in STP	First order, standard OECD/EU tests		D
Rate constant for biodegradation in STP	0	[d-1]	O
Total rate constant for degradation in STP	0	[d-1]	O
Maximum growth rate of specific microorganisms	2	[d-1]	D
Half saturation concentration	0.5	[g.m-3]	D
WATER/SEDIMENT			
WATER			
Rate constant for hydrolysis in surface water	6.93E-07	[d-1] (12[oC])	O
Rate constant for photolysis in surface water	6.93E-07	[d-1]	O
Rate constant for biodegradation in surface water	0	[d-1] (12[oC])	O
Total rate constant for degradation in bulk surface water	1.39E-06	[d-1] (12[oC])	O
Rate constant for biodegradation in saltwater	0	[d-1] (12[oC])	O
Total rate constant for degradation in bulk saltwater	1.39E-06	[d-1] (12[oC])	O
SEDIMENT			
Rate constant for biodegradation in aerated sediment	6.93E-07	[d-1] (12[oC])	O
Total rate constant for degradation in bulk sediment	6.93E-08	[d-1] (12[oC])	O
AIR			
Specific degradation rate constant with OH-radicals	0	[cm3.molec-1.s-1]	D
Rate constant for degradation in air	0	[d-1]	O

SOIL				
Rate constant for biodegradation in bulk soil		1.00E+06	[d] (DT50,12[oC])	O
Total rate constant for degradation in bulk soil		1.00E+06	[d] (DT50,12[oC])	O
REMOVAL RATE CONSTANTS SOIL				
Total rate constant for degradation in bulk soil		1.00E+06	[d] (DT50,12[oC])	O
Rate constant for volatilisation from agricultural soil		1.62E-12	[d-1]	O
Rate constant for leaching from agricultural soil		1.33E-05	[d-1]	O
Total rate constant for removal from agricultural top soil		1.40E-05	[d-1]	O
Rate constant for volatilisation from grassland soil		3.23E-12	[d-1]	O
Rate constant for leaching from grassland soil		2.66E-05	[d-1]	O
Total rate constant for removal from grassland top soil		2.73E-05	[d-1]	O
Rate constant for volatilisation from industrial soil		6.47E-12	[d-1]	O
Rate constant for leaching from industrial soil		5.32E-05	[d-1]	O
Total rate constant for removal from industrial soil		5.39E-05	[d-1]	O
RELEASE ESTIMATION				
BIOCIDE SCENARIO **INPUT DATA**				
Usage/production title				D
Scenario choice for biocides		(8) Wood preservatives		S
Additional scenario information		(8.2.2) Treated wood, noise barrier		S
SERVICE LIFE				
Emission scenario		Local wastewater emission and application soil concentration		S
INTERMEDIATE RESULTS				
RELEASE FRACTIONS AND EMISSION DAYS				
SERVICE LIFE				
INPUT				
Average daily flux, initial assessment period		0.3902	[mg.m-2.d-1]	S
Average daily flux, chronic assessment period		??	[g.m-2.d-1]	D
CALCULATIONS				

Wet soil mass		4.25E+05	[kgwwt]	O
Average rate of active ingredient leached out (initial period)		3.90E-03	[kg.d-1]	O
Average rate of active ingredient leached out (chronic period)		??	[kg.d-1]	O
Local emission from to wastewater, initial period		3.90E-03	[kg.d-1]	O
Local emission from to wastewater, longer period		??	[kg.d-1]	O
Concentration of substance in soil, initial period		0	[mg.kgwwt-1]	O
Concentration of substance in soil, longer period		??	[mg.kgwwt-1]	O
Local emission to wastewater during episode		3.90E-03	[kg.d-1]	O
Concentration in industrial/application soil		0	[mg.kgwwt-1]	O
Number of emission days per year		30	[-]	O
WITH DEGRADATION				
Total rate constant for removal from soil		3.09E+05	[hr] (DT50)	O
Soil concentration, initial period, with degradation		0.138	[mg.kgwwt-1]	O
Soil concentration, longer period, with degradation		??	[mg.kgwwt-1]	O
Average conc. in soil pore water, initial period, with degredation		1.30E-03	[mg.l-1]	O
Average conc. in soil pore water, longer period, with degredation		??	[mg.l-1]	O
DEFAULTS				
Leachable wood area		1.00E+04	[m2]	S
Depth of receiving soil compartment		0.5	[m]	D
Width of receiving soil compartment		0.5	[m]	D
Volume of soil		250	[m3]	O
Fraction of tonnage released to industrial soil		0	[-]	S
Fraction of tonnage released to wastewater		1	[-]	S
Number of emission days, initial period		30	[d]	D
Number of emission days, longer period		365	[d]	D
LOCAL				
[SERVICE LIFE]				
Local emission to air during episode		0	[kg.d-1]	O
Emission to air calculated by special scenario		No		O
Local emission to wastewater during episode		3.90E-03	[kg.d-1]	O

Emission to water calculated by special scenario		Yes		O
Specific biocides scenario available		Yes		D
Show this step in further calculations		Yes		O
Intermittent release		No		D
INPUT AND CONFIGURATION [SERVICE LIFE]				
INPUT				
Use or bypass STP (local freshwater assessment)		Use STP		D
Use or bypass STP (local marine assessment)		Bypass STP		D
Local emission to wastewater during episode		3.90E-03	[kg.d-1]	O
Concentration in untreated wastewater		1.95E-03	[mg.l-1]	O
Local emission entering the STP		3.90E-03	[kg.d-1]	O
CONFIGURATION				
Type of local STP		With primary settler (9-box)		D
Number of inhabitants feeding this STP		1.00E+04	[eq]	O
Effluent discharge rate of this STP		2.00E+06	[l.d-1]	O
Calculate dilution from river flow rate		No		O
Flow rate of the river		1.80E+04	[m3.d-1]	O
Dilution factor (rivers)		10	[-]	O
Dilution factor (coastal areas)		100	[-]	O
OUTPUT [SERVICE LIFE]				
Fraction of emission directed to air by STP		1.69E-09	[%]	O
Fraction of emission directed to water by STP		58.6	[%]	O
Fraction of emission directed to sludge by STP		41.4	[%]	O
Fraction of the emission degraded in STP		0	[%]	O
Total of fractions		100	[%]	O
Local indirect emission to air from STP during episode		6.61E-14	[kg.d-1]	O
Concentration in untreated wastewater		1.95E-03	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent		1.14E-03	[mg.l-1]	O
Concentration in effluent exceeds solubility		No		O
Concentration in dry sewage sludge		2.05	[mg.kg-1]	O

PEC for micro-organisms in the STP		1.14E-03	[mg.l-1]	O
LIFE CYCLE STEPS				
[SERVICE LIFE]				
LOCAL CONCENTRATIONS AND DEPOSITIONS [SERVICE LIFE]				
AIR				
Concentration in air during emission episode		1.84E-17	[mg.m-3]	O
Annual average concentration in air, 100 m from point source		1.51E-18	[mg.m-3]	O
Total deposition flux during emission episode		3.14E-16	[mg.m-2.d-1]	O
Annual average total deposition flux		2.58E-17	[mg.m-2.d-1]	O
WATER, SEDIMENT				
Concentration in surface water during emission episode (dissolved)		1.13E-04	[mg.l-1]	O
Concentration in surface water exceeds solubility		No		O
Annual average concentration in surface water (dissolved)		9.31E-06	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)		1.93E-05	[mg.l-1]	O
Annual average concentration in seawater (dissolved)		1.59E-06	[mg.l-1]	O
SOIL, GROUNDWATER				
Concentration in agric. soil averaged over 30 days		0.0294	[mg.kgwwt-1]	O
Concentration in agric. soil averaged over 180 days		0.0294	[mg.kgwwt-1]	O
Concentration in grassland averaged over 180 days		0.0115	[mg.kgwwt-1]	O
Fraction of steady-state (agricultural soil)		0.0498	[-]	O
Fraction of steady-state (grassland soil)		0.0948	[-]	O
Concentration in industrial/application soil		0	[mg.kgwwt-1]	O
LOCAL PECS [SERVICE LIFE]				
AIR				
Annual average local PEC in air (total)		1.51E-18	[mg.m-3]	O
WATER, SEDIMENT				
Local PEC in surface water during emission episode (dissolved)		1.13E-04	[mg.l-1]	O
Qualitative assessment might be		No		O

needed (TGD Part II, 5.6)				
Annual average local PEC in surface water (dissolved)		9.31E-06	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode		0.0149	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)		1.93E-05	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)		No		O
Annual average local PEC in seawater (dissolved)		1.59E-06	[mg.l-1]	O
Local PEC in marine sediment during emission episode		2.54E-03	[mg.kgwwt-1]	O
SOIL, GROUNDWATER				
Local PEC in agric. soil (total) averaged over 30 days		0.0294	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days		0.0294	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days		0.0115	[mg.kgwwt-1]	O
Local PEC in industrial/application soil		0	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil		2.77E-04	[mg.l-1]	O
Local PEC in pore water of grassland		1.08E-04	[mg.l-1]	O
Local PEC in groundwater under agricultural soil		2.77E-04	[mg.l-1]	O
Local PEC in pore water of industrial/application soil		0	[mg.l-1]	O
PNECs	**Value**	**Unit**	**PECs**	**RC**
PNECwater	**0.029**	**mg/l**	**0.00011**	**0.00390**
PNECstp	**0.09**	**mg/l**	**0.00114**	**0.01267**
PNECsoil	**0.408**	**mg/kg soil dw**	**0.03322**	**0.08143**
Drinking water limit: 0.1 µg/l = 0.0001 mg/L	**0.0001**	**mg/L**	**0.00028**	**---**

- a realistic worst case assumption of bypassing the STP

Table 2.6.3-4: EUSES Output file: Multi-storey building in the city, direct release to surface water (bypass STP)

(abbreviations: S: set; D: default; O: output; I: input)

Section/parameter		**Actual value**	**Unit**	**Stat**
STUDY				
STUDY IDENTIFICATION				
Study name		K-HDO		S
Study description		Xyligen		S
DEFAULTS	See table above			
RELEASE ESTIMATION				
BIOCIDE SCENARIO INPUT DATA				
Usage/production title				D
Scenario choice for biocides		(8) Wood preservatives		S
Additional scenario information		(8.2.2) Treated wood, noise barrier		S
SERVICE LIFE				
Emission scenario		Local wastewater emission and application soil concentration		S
INTERMEDIATE RESULTS				
RELEASE FRACTIONS AND EMISSION DAYS				
SERVICE LIFE				
INPUT				
Average daily flux, initial assessment period		0.3902	[mg.m-2.d-1]	S
Average daily flux, chronic assessment period		??	[g.m-2.d-1]	D
CALCULATIONS				
Wet soil mass		4.25E+05	[kgwwt]	O
Average rate of active ingredient leached out (initial period)		3.90E-03	[kg.d-1]	O
Average rate of active ingredient leached out (chronic period)		??	[kg.d-1]	O
Local emission from to wastewater, initial period		3.90E-03	[kg.d-1]	O
Local emission from to wastewater, longer period		??	[kg.d-1]	O
Concentration of substance in soil, initial period		0	[mg.kgwwt-1]	O
Concentration of substance in soil,		??	[mg.kgwwt-1]	O

longer period			
Local emission to wastewater during episode	3.90E-03	[kg.d-1]	O
Concentration in industrial/application soil	0	[mg.kgwwt-1]	O
Number of emission days per year	30	[-]	O
WITH DEGRADATION			
Total rate constant for removal from soil	3.09E+05	[hr] (DT50)	O
Soil concentration, initial period, with degradation	0.138	[mg.kgwwt-1]	O
Soil concentration, longer period, with degradation	??	[mg.kgwwt-1]	O
Average conc. in soil pore water, initial period, with degredation	1.30E-03	[mg.l-1]	O
Average conc. in soil pore water, longer period, with degredation	??	[mg.l-1]	O
DEFAULTS			
Leachable wood area	1.00E+04	[m2]	S
Depth of receiving soil compartment	0.5	[m]	D
Width of receiving soil compartment	0.5	[m]	D
Volume of soil	250	[m3]	O
Fraction of tonnage released to industrial soil	0	[-]	S
Fraction of tonnage released to wastewater	1	[-]	S
Number of emission days, initial period	30	[d]	D
Number of emission days, longer period	365	[d]	D
LOCAL			
[SERVICE LIFE]			
Local emission to air during episode	0	[kg.d-1]	O
Emission to air calculated by special scenario	No		O
Local emission to wastewater during episode	3.90E-03	[kg.d-1]	O
Emission to water calculated by special scenario	Yes		O
Specific biocides scenario available	Yes		D
Show this step in further calculations	Yes		O
Intermittent release	No		D
[SERVICE LIFE]			
INPUT AND CONFIGURATION [SERVICE LIFE]			
INPUT			

Use or bypass STP (local freshwater assessment)	Bypass STP		S
Use or bypass STP (local marine assessment)	Bypass STP		D
Local emission to wastewater during episode	3.90E-03	[kg.d-1]	O
Concentration in untreated wastewater	1.95E-03	[mg.l-1]	O
Local emission entering the STP	3.90E-03	[kg.d-1]	O
CONFIGURATION			
Type of local STP	With primary settler (9-box)		D
Number of inhabitants feeding this STP	1.00E+04	[eq]	O
Effluent discharge rate of this STP	2.00E+06	[l.d-1]	O
Calculate dilution from river flow rate	No		O
Flow rate of the river	1.80E+04	[m3.d-1]	O
Dilution factor (rivers)	10	[-]	O
Dilution factor (coastal areas)	100	[-]	O
OUTPUT [SERVICE LIFE]			
Fraction of emission directed to air by STP	0	[%]	O
Fraction of emission directed to water by STP	100	[%]	O
Fraction of emission directed to sludge by STP	0	[%]	O
Fraction of the emission degraded in STP	0	[%]	O
Total of fractions	100	[%]	O
Local indirect emission to air from STP during episode	0	[kg.d-1]	O
Concentration in untreated wastewater	1.95E-03	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent	1.95E-03	[mg.l-1]	O
Concentration in effluent exceeds solubility	No		O
Concentration in dry sewage sludge	0	[mg.kg-1]	O
PEC for micro-organisms in the STP	1.95E-03	[mg.l-1]	O
LIFE CYCLE STEPS			
[SERVICE LIFE]			
LOCAL CONCENTRATIONS AND DEPOSITIONS [SERVICE LIFE]			
AIR			
Concentration in air during emission episode	0	[mg.m-3]	O
Annual average concentration in air, 100 m from point source	0	[mg.m-3]	O
Total deposition flux during emission episode	0	[mg.m-2.d-1]	O
Annual average total deposition flux	0	[mg.m-2.d-1]	O
WATER, SEDIMENT			
Concentration in surface water during emission	1.93E-04	[mg.l-1]	O

episode (dissolved)			
Concentration in surface water exceeds solubility	No		O
Annual average concentration in surface water (dissolved)	1.59E-05	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)	1.93E-05	[mg.l-1]	O
Annual average concentration in seawater (dissolved)	1.59E-06	[mg.l-1]	O
SOIL, GROUNDWATER			
Concentration in agric. soil averaged over 30 days	0	[mg.kgwwt-1]	O
Concentration in agric. soil averaged over 180 days	0	[mg.kgwwt-1]	O
Concentration in grassland averaged over 180 days	0	[mg.kgwwt-1]	O
Fraction of steady-state (agricultural soil)	??	[-]	O
Fraction of steady-state (grassland soil)	??	[-]	O
Concentration in industrial/application soil	0	[mg.kgwwt-1]	O
LOCAL PECS [SERVICE LIFE]			
AIR			
Annual average local PEC in air (total)	0	[mg.m-3]	O
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	1.93E-04	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	1.59E-05	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode	0.0254	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)	1.93E-05	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	1.59E-06	[mg.l-1]	O
Local PEC in marine sediment during emission episode	2.54E-03	[mg.kgwwt-1]	O
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	0	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	0	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	0	[mg.kgwwt-1]	O
Local PEC in industrial/application soil	0	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	0	[mg.l-1]	O
Local PEC in pore water of grassland	0	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	0	[mg.l-1]	O
Local PEC in pore water of industrial/application soil	0	[mg.l-1]	O

PNECs	**Value**	**Unit**	**PECs**	**RC**
PNECwater	**0.029**	**mg/l**	**0.00019**	**0.00666**

2. Realistic Scenario

According to the applicant for the length Spittelauer Lände of 28.32 m, 12 standard sized boards are necessary. For the length Ingen Housz Gasse of 32.25 m, 13 standard sized boards are necessary. For the length Patio of 18.5 m, 8 standard sized boards are necessary. For the length Patio of 17 m, 7 standard sized boards are necessary. For the length Patio of 17.6 m, 7 standard sized boards are necessary. For 1 stage of the scaffold a total of 47 boards are necessary. It is assumed that each stage of scaffolds should have a height of approx. 2-2.2 metres. Therefore for the requested house with a height of 25.31 m, 11 scaffold stages are required. In this case the total scaffolding board surface is (47 x 11 x 2.5 x 0.6 m) = 775.5 m².

It should be kept in mind that the last above given scenario describes a realistic worst case emission scenario for the following reason:

- Higher stages will protect deeper stages from rain fall. Therefore only a limited number of stages (e.g. two of eleven) will practically have a share in the overall emission.

The PECs were calculated with EUSES 2.1.The EUSES Output file for the estimation of direct emissions to STP can be found in 2.6.3-5 and the bypass-STP scenario can be found in table 2.6.3.6.

Table 2.6.3-5: EUSES Output file: Multi-storey building in the city, direct release to STP

(abbreviations: S: set; D: default; O: output; I: input)

Section/parameter		**Actual value**	**Unit**	**Stat**
STUDY				
STUDY IDENTIFICATION				
Study name		K-HDO		S
Study description		Xyligen 30 F		S
DEFAULTS	See table above			
RELEASE ESTIMATION				
BIOCIDE SCENARIO INPUT DATA				
Usage/production title				D
Scenario choice for biocides		(8) Wood preservatives		S
Additional scenario information		(8.2.2) Treated wood, noise barrier		S
SERVICE LIFE				
Emission scenario		Local wastewater emission and application soil concentration		S
INTERMEDIATE RESULTS				
RELEASE FRACTIONS AND EMISSION DAYS				
SERVICE LIFE				
INPUT				
Average daily flux, initial assessment period		0.3902	[mg.m-2.d-1]	S
Average daily flux, chronic assessment period		??	[g.m-2.d-1]	D

CALCULATIONS				
Wet soil mass		4.25E+05	[kgwwt]	O
Average rate of active ingredient leached out (initial period)		3.03E-04	[kg.d-1]	O
Average rate of active ingredient leached out (chronic period)		??	[kg.d-1]	O
Local emission from to wastewater, initial period		3.03E-04	[kg.d-1]	O
Local emission from to wastewater, longer period		??	[kg.d-1]	O
Concentration of substance in soil, initial period		0	[mg.kgwwt-1]	O
Concentration of substance in soil, longer period		??	[mg.kgwwt-1]	O
Local emission to wastewater during episode		3.03E-04	[kg.d-1]	O
Concentration in industrial/application soil		0	[mg.kgwwt-1]	O
Number of emission days per year		30	[-]	O
WITH DEGRADATION				
Total rate constant for removal from soil		3.09E+05	[hr] (DT50)	O
Soil concentration, initial period, with degradation		0.0107	[mg.kgwwt-1]	O
Soil concentration, longer period, with degradation		??	[mg.kgwwt-1]	O
Average conc. in soil pore water, initial period, with degredation		1.01E-04	[mg.l-1]	O
Average conc. in soil pore water, longer period, with degredation		??	[mg.l-1]	O
DEFAULTS				
Leachable wood area		775.5	[m2]	S
Depth of receiving soil compartment		0.5	[m]	D
Width of receiving soil compartment		0.5	[m]	D
Volume of soil		250	[m3]	O
Fraction of tonnage released to industrial soil		0	[-]	S
Fraction of tonnage released to wastewater		1	[-]	S
Number of emission days, initial period		30	[d]	D
Number of emission days, longer period		365	[d]	D
REGIONAL AND CONTINENTAL RELEASES				
SERVICE LIFE				
REGIONAL				
Regional release to air		0	[kg.d-1]	O
Regional release to wastewater		0	[kg.d-1]	O
Regional release to surface water		0	[kg.d-1]	O
Regional release to industrial soil		0	[kg.d-1]	O
Regional release to agricultural soil		0	[kg.d-1]	O
CONTINENTAL				
Continental release to air		0	[kg.d-1]	O
Continental release to wastewater		0	[kg.d-1]	O
Continental release to surface water		0	[kg.d-1]	O
Continental release to industrial soil		0	[kg.d-1]	O

Continental release to agricultural soil	0	[kg.d-1]	O
REGIONAL AND CONTINENTAL TOTAL EMISSIONS			
Total regional emission to air	0	[kg.d-1]	O
Total regional emission to wastewater	0	[kg.d-1]	O
Total regional emission to surface water	0	[kg.d-1]	O
Total regional emission to industrial soil	0	[kg.d-1]	O
Total regional emission to agricultural soil	0	[kg.d-1]	O
Total continental emission to air	0	[kg.d-1]	O
Total continental emission to wastewater	0	[kg.d-1]	O
Total continental emission to surface water	0	[kg.d-1]	O
Total continental emission to industrial soil	0	[kg.d-1]	O
Total continental emission to agricultural soil	0	[kg.d-1]	O
LOCAL			
[SERVICE LIFE]			
Local emission to air during episode	0	[kg.d-1]	O
Emission to air calculated by special scenario	No		O
Local emission to wastewater during episode	3.03E-04	[kg.d-1]	O
Emission to water calculated by special scenario	Yes		O
Specific biocides scenario available	Yes		D
Show this step in further calculations	Yes		O
Intermittent release	No		D
DISTRIBUTION			
SEWAGE TREATMENT			
CONTINENTAL			
Fraction of emission directed to air	0	[%]	O
Fraction of emission directed to water	0	[%]	O
Fraction of emission directed to sludge	0	[%]	O
Fraction of the emission degraded	0	[%]	O
Total of fractions	0	[%]	O
Indirect emission to air	0	[kg.d-1]	O
Indirect emission to surface water	0	[kg.d-1]	O
Indirect emission to agricultural soil	0	[kg.d-1]	O
REGIONAL			
Fraction of emission directed to air	0	[%]	O
Fraction of emission directed to water	0	[%]	O
Fraction of emission directed to sludge	0	[%]	O
Fraction of the emission degraded	0	[%]	O
Total of fractions	0	[%]	O
Indirect emission to air	0	[kg.d-1]	O
Indirect emission to surface water	0	[kg.d-1]	O
Indirect emission to agricultural soil	0	[kg.d-1]	O

[SERVICE LIFE]			
INPUT AND CONFIGURATION [SERVICE LIFE]			
INPUT			
Use or bypass STP (local freshwater assessment)	Use STP		D
Use or bypass STP (local marine assessment)	Bypass STP		D
Local emission to wastewater during episode	3.03E-04	[kg.d-1]	O
Concentration in untreated wastewater	1.51E-04	[mg.l-1]	O
Local emission entering the STP	3.03E-04	[kg.d-1]	O
CONFIGURATION			
Type of local STP	With primary settler (9-box)		D
Number of inhabitants feeding this STP	1.00E+04	[eq]	O
Effluent discharge rate of this STP	2.00E+06	[l.d-1]	O
Calculate dilution from river flow rate	No		O
Flow rate of the river	1.80E+04	[m3.d-1]	O
Dilution factor (rivers)	10	[-]	O
Dilution factor (coastal areas)	100	[-]	O
OUTPUT [SERVICE LIFE]			
Fraction of emission directed to air by STP	1.69E-09	[%]	O
Fraction of emission directed to water by STP	58.6	[%]	O
Fraction of emission directed to sludge by STP	41.4	[%]	O
Fraction of the emission degraded in STP	0	[%]	O
Total of fractions	100	[%]	O
Local indirect emission to air from STP during episode	5.13E-15	[kg.d-1]	O
Concentration in untreated wastewater	1.51E-04	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent	8.86E-05	[mg.l-1]	O
Concentration in effluent exceeds solubility	No		O
Concentration in dry sewage sludge	0.159	[mg.kg-1]	O
PEC for micro-organisms in the STP	8.86E-05	[mg.l-1]	O
LIFE CYCLE STEPS			
[SERVICE LIFE]			
LOCAL CONCENTRATIONS AND DEPOSITIONS [SERVICE LIFE]			
AIR			
Concentration in air during emission episode	1.43E-18	[mg.m-3]	O
Annual average concentration in air, 100 m from point source	1.17E-19	[mg.m-3]	O
Total deposition flux during emission episode	2.44E-17	[mg.m-2.d-1]	O
Annual average total deposition flux	2.00E-18	[mg.m-2.d-1]	O
WATER, SEDIMENT			
Concentration in surface water during emission episode (dissolved)	8.78E-06	[mg.l-1]	O
Concentration in surface water exceeds solubility	No		O

Annual average concentration in surface water (dissolved)		7.22E-07	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)		1.50E-06	[mg.l-1]	O
Annual average concentration in seawater (dissolved)		1.23E-07	[mg.l-1]	O
SOIL, GROUNDWATER				
Concentration in agric. soil averaged over 30 days		2.28E-03	[mg.kgwwt-1]	O
Concentration in agric. soil averaged over 180 days		2.28E-03	[mg.kgwwt-1]	O
Concentration in grassland averaged over 180 days		8.91E-04	[mg.kgwwt-1]	O
Fraction of steady-state (agricultural soil)		0.0498	[-]	O
Fraction of steady-state (grassland soil)		0.0948	[-]	O
Concentration in industrial/application soil		0	[mg.kgwwt-1]	O
LOCAL PECS [SERVICE LIFE]				
AIR				
Annual average local PEC in air (total)		1.17E-19	[mg.m-3]	O
WATER, SEDIMENT				
Local PEC in surface water during emission episode (dissolved)		8.78E-06	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)		No		O
Annual average local PEC in surface water (dissolved)		7.22E-07	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode		1.15E-03	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)		1.50E-06	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)		No		O
Annual average local PEC in seawater (dissolved)		1.23E-07	[mg.l-1]	O
Local PEC in marine sediment during emission episode		1.97E-04	[mg.kgwwt-1]	O
SOIL, GROUNDWATER				
Local PEC in agric. soil (total) averaged over 30 days		2.28E-03	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days		2.28E-03	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days		8.91E-04	[mg.kgwwt-1]	O
Local PEC in industrial/application soil		0	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil		2.15E-05	[mg.l-1]	O
Local PEC in pore water of grassland		8.40E-06	[mg.l-1]	O
Local PEC in groundwater under agricultural soil		2.15E-05	[mg.l-1]	O
PNECs	**Value**	**Unit**	**PECs**	**RC**
PNECwater	0.029	mg/l	0.00001	0.00030
PNECstp	0.09	mg/l	0.00009	0.00098

PNECsoil	0.408	mg/kg soil dw	0.00258	0.00631
Drinking water limit: 0.1 µg/l = 0.0001 mg/L	0.0001	mg/L	0.00002	ok

Table 2.6.3-6: EUSES Output file: Multi-storey building in the city, direct release to surface water (bypass STP)

(abbreviations: S: set; D: default; O: output; I: input)

Section/parameter		**Actual value**	**Unit**	**Stat**
STUDY				
STUDY IDENTIFICATION				
Study name		K-HDO		S
Study description		Xyligen 30 F		S
DEFAULTS	See table above			
RELEASE ESTIMATION				
BIOCIDE SCENARIO INPUT DATA				
Usage/production title				D
Scenario choice for biocides		(8) Wood preservatives		S
Additional scenario information		(8.2.2) Treated wood, noise barrier		S
SERVICE LIFE				
Emission scenario		Local wastewater emission and application soil concentration		S
INTERMEDIATE RESULTS				
RELEASE FRACTIONS AND EMISSION DAYS				
SERVICE LIFE				
INPUT				
Average daily flux, initial assessment period		0.3902	[mg.m-2.d-1]	S
Average daily flux, chronic assessment period		??	[g.m-2.d-1]	D
CALCULATIONS				
Wet soil mass		4.25E+05	[kgwwt]	O
Average rate of active ingredient leached out (initial period)		3.03E-04	[kg.d-1]	O
Average rate of active ingredient leached out (chronic period)		??	[kg.d-1]	O
Local emission from to wastewater, initial period		3.03E-04	[kg.d-1]	O
Local emission from to wastewater, longer period		??	[kg.d-1]	O
Concentration of substance in soil, initial period		0	[mg.kgwwt-1]	O
Concentration of substance in soil, longer period		??	[mg.kgwwt-1]	O
Local emission to wastewater during episode		3.03E-04	[kg.d-1]	O
Concentration in industrial/application soil		0	[mg.kgwwt-1]	O
Number of emission days per		30	[-]	O

year				
WITH DEGRADATION				
Total rate constant for removal from soil		3.09E+05	[hr] (DT50)	O
Soil concentration, initial period, with degradation		0.0107	[mg.kgwwt-1]	O
Soil concentration, longer period, with degradation		??	[mg.kgwwt-1]	O
Average conc. in soil pore water, initial period, with degredation		1.01E-04	[mg.l-1]	O
Average conc. in soil pore water, longer period, with degredation		??	[mg.l-1]	O
DEFAULTS				
Leachable wood area		775.5	[m2]	S
Depth of receiving soil compartment		0.5	[m]	D
Width of receiving soil compartment		0.5	[m]	D
Volume of soil		250	[m3]	O
Fraction of tonnage released to industrial soil		0	[-]	S
Fraction of tonnage released to wastewater		1	[-]	S
Number of emission days, initial period		30	[d]	D
Number of emission days, longer period		365	[d]	D
LOCAL				
[SERVICE LIFE]				
Local emission to air during episode		0	[kg.d-1]	O
Emission to air calculated by special scenario		No		O
Local emission to wastewater during episode		3.03E-04	[kg.d-1]	O
Emission to water calculated by special scenario		Yes		O
Specific biocides scenario available		Yes		D
Show this step in further calculations		Yes		O
Intermittent release		No		D
[SERVICE LIFE]				
INPUT AND CONFIGURATION [SERVICE LIFE]				
INPUT				
Use or bypass STP (local freshwater assessment)		Bypass STP		S
Use or bypass STP (local marine assessment)		Bypass STP		D
Local emission to wastewater during episode		3.03E-04	[kg.d-1]	O
Concentration in untreated wastewater		1.51E-04	[mg.l-1]	O
Local emission entering the STP		3.03E-04	[kg.d-1]	O

CONFIGURATION				
Type of local STP		With primary settler (9-box)		D
Number of inhabitants feeding this STP		1.00E+04	[eq]	O
Effluent discharge rate of this STP		2.00E+06	[l.d-1]	O
Calculate dilution from river flow rate		No		O
Flow rate of the river		1.80E+04	[m3.d-1]	O
Dilution factor (rivers)		10	[-]	O
Dilution factor (coastal areas)		100	[-]	O
OUTPUT [SERVICE LIFE]				
Fraction of emission directed to air by STP		0	[%]	O
Fraction of emission directed to water by STP		100	[%]	O
Fraction of emission directed to sludge by STP		0	[%]	O
Fraction of the emission degraded in STP		0	[%]	O
Total of fractions		100	[%]	O
Local indirect emission to air from STP during episode		0	[kg.d-1]	O
Concentration in untreated wastewater		1.51E-04	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent		1.51E-04	[mg.l-1]	O
Concentration in effluent exceeds solubility		No		O
Concentration in dry sewage sludge		0	[mg.kg-1]	O
PEC for micro-organisms in the STP		1.51E-04	[mg.l-1]	O
LIFE CYCLE STEPS				
[SERVICE LIFE]				
LOCAL CONCENTRATIONS AND DEPOSITIONS [SERVICE LIFE]				
AIR				
Concentration in air during emission episode		0	[mg.m-3]	O
Annual average concentration in air, 100 m from point source		0	[mg.m-3]	O
Total deposition flux during emission episode		0	[mg.m-2.d-1]	O
Annual average total deposition flux		0	[mg.m-2.d-1]	O
WATER, SEDIMENT				
Concentration in surface water during emission episode (dissolved)		1.50E-05	[mg.l-1]	O
Concentration in surface water exceeds solubility		No		O
Annual average concentration in surface water (dissolved)		1.23E-06	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)		1.50E-06	[mg.l-1]	O
Annual average concentration in seawater (dissolved)		1.23E-07	[mg.l-1]	O

SOIL, GROUNDWATER				
Concentration in agric. soil averaged over 30 days		0	[mg.kgwwt-1]	O
Concentration in agric. soil averaged over 180 days		0	[mg.kgwwt-1]	O
Concentration in grassland averaged over 180 days		0	[mg.kgwwt-1]	O
Fraction of steady-state (agricultural soil)		??	[-]	O
Fraction of steady-state (grassland soil)		??	[-]	O
Concentration in industrial/application soil		0	[mg.kgwwt-1]	O
LOCAL PECS [SERVICE LIFE]				
AIR				
Annual average local PEC in air (total)		0	[mg.m-3]	O
WATER, SEDIMENT				
Local PEC in surface water during emission episode (dissolved)		1.50E-05	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)		No		O
Annual average local PEC in surface water (dissolved)		1.23E-06	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode		1.97E-03	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)		1.50E-06	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)		No		O
Annual average local PEC in seawater (dissolved)		1.23E-07	[mg.l-1]	O
Local PEC in marine sediment during emission episode		1.97E-04	[mg.kgwwt-1]	O
SOIL, GROUNDWATER				
Local PEC in agric. soil (total) averaged over 30 days		0	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days		0	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days		0	[mg.kgwwt-1]	O
Local PEC in industrial/application soil		0	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil		0	[mg.l-1]	O
Local PEC in pore water of grassland		0	[mg.l-1]	O
Local PEC in groundwater under agricultural soil		0	[mg.l-1]	O
Local PEC in pore water of industrial/application soil		0	[mg.l-1]	O
PNECs	**Value**	**Unit**	**PECs**	**RC**
PNECwater	0.029	mg/l	0.00002	0.00052

2.7 Risk assessment for human health

If new data/information on human health and exposure are required for the product or for the active substance(s) due to differences in product composition and/or intended use (compared to representative product(s) for Annex I inclusion) these new data/information should be evaluated and the results of the resulting risk assessments summarised here. The format of this summary should preferably follow the pattern of Documents II-A, II-B and II-C of a CAR (i.e. effect, exposure, risk).

If no new data/information are required and if the product applied for authorisation is identical to the example product in the CAR a very short summary of the human health risk assessment can be presented here which could be copied from the assessment report or from the CAR.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism" must be taken into consideration.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product does not contain substances of concern.

2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.
The basis for the health assessment of the biocidal product is laid out in Annex 5 "Toxicology – biocidal product"

2.7.2 Exposure

The biocidal product contains the active substance K-HDO (pure: 300 g/kg) and no substances of concern. For details, please see chapter 2.6 of this document.

2.7.2.1 Exposure of professional users

In Annex 6„Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out. For details, please see chapter 2.6 of this document.

2.7.2.2 Exposure of non-professional users and the general public

In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out. For details, please see chapter 2.6 of this document.

2.7.2.3 Exposure to residues in food

In Annex 8 “Residue behaviour”, the results of the residue assessment are laid out.
For details, please see chapter 2.6.1 and 2.6.2 of this document. No exposure to residues in food could be identified.

2.7.3 Risk Characterisation

With proper use of Xyligen 30 F in accordance with the use instructions harmful effects on the health of users and third parties are not expected. The estimated exposures for the intended use are compared to the respective systemic AEL for the active substance K-HDO that is the only product constituent of toxicological concern.

In comparison to the Competent Authority Report accompanying the Annex I inclusion, the following changes were introduced:

- The max. applied amount per treatment is 2.85 kg a.s./m³ wood composite instead of 2.6 kg a.s./m³ wood composite.
- The additional coating which is proposed for use class 3.1 is not considered in human exposure assessment.
- The standard factor for penetration of PPE (gloves) was reduced from 12% to 10%, based on a harmonised decision at the Biocides Technical Meetings.

2.7.3.1 Risk for local effects – qualitative evaluation

Since the biocidal product Xyligen 30 F and the active substance K-HDO (as only ingredient of potential toxicological concern) is irritating to rabbit skin after 20 hours application and can cause severe eye damage, local effects on the skin and respiratory tract may be expected.

Dermal exposure

With primary exposure from the sporadic intervention with the fully automatic glue line addition system appropriate clean gloves are necessary to protect against mechanical injury and local dermal irritation.

Dermal exposure to treated wood composites may result in concentrations of 1 µg/cm^2 K-HDO (tier 3 estimate from measured data, wipe test, see chapter 2.6 above). No quantitatively reliable point of departure is available for the derivation of a dermal AEC. However in qualitative terms the risk is considered acceptable since no irritation was observed after acute exposure to Xyligen 30F (30% K-HDO) for 15 minutes to rabbit skin in vivo and no irritation was observed in the local lymph node assay with a 25% K-HDO solution (37.5 mg) applied for 3 consecutive days to the dorsum of the mouse ear. The effects of Xyligen 30F (30% K-HDO) observed after 20 hours application to the rabbit skin test were judged as irritant and not corrosive (mg/2.5cm^2 unclear).

Inhalation exposure

Outdoor exposure or appropriate ventilation systems reducing concentration in air below 0.057 ng K-HDO/L (tier 2 estimate = 1% of saturation concentration) should prevent local respiratory effects considering that within a inhalatory 28 day rat study no clinical symptoms and no local histopathological effects in the respiratory tract were reported at concentrations of 2 mg/L for 6 hours per day.

The 2 mg/L value contains uncertainty with regard to intra- and interspecies variability as well as analytical exposure concentrations (only nominal concentrations given). Consequently it is not considered an appropriate point of departure for a quantitative local AEC for K-HDO. However since adverse effects were observed in the study (see CAR doc IIIA6.3.3, the effects observed at this dose level were: total lipids ↓, alkaline phosphatase↑, urine sediment round epithelia ↑ (m) and leucocytes↑ (f), liver weight ↓, liver necrosis (3f), lung foam cells number↑ (m)) and given the large margin between the 2 mg/L value and the exposure estimate of 0.057 ng/L, the study is considered adequate for a qualitative discussion of risk for local effects.

Oral exposure

Oral exposure to Xyligen 30F (30% K-HDO) is unlikely due to the intended use with wood composites for construction. However assuming an infant gets by accident access to treated wood composites and chews a piece of 4x4x1 cm the respective tier 2 exposure estimate resulted in 0.46 mg K-HDO/kg bw (see chapter 2.6 above). This amount should not necessarily cause unacceptable local GI effects after accidental single exposure situations, since neither at 90 mg K-HDO/kg bw day applied in a 28 day rat feeding study, nor at 25 mg K-HDO/kg bw day applied in a 90 day rat gavage study histopatholoigcal effects were observed in the gastrointestinal tract of the rat.

2.7.3.2 Risk for systemic effects from primary exposure (industrial use)

The applicant stated that Xyligen 30 F is only applied during the manufacturing of wood composites in fully automatic glue line addition systems.

Inhalation exposure is limited by appropriate ventilation systems. However exposure was calculated at the saturation concentration of the active substance K-HDO in air (tier 1) and refined with 1% of the saturation concentration (tier 2).

Similarly dermal exposure is limited. It is not part of work routine but happens sporadically with interventions in case the normally fully automatic system does not work properly. For worst case consideration the dermal exposure of a manual filling and loading procedure as well as the direct contact of workers with treated panels were considered (see chapter 2.7.2 above). However these exposure situations are sporadic, thus they do not happen daily and not subsequently to the same worker.

Consequently for the risk assessment for systemic effects from potential daily inhalation exposure the $\text{AEL}_{\text{long term}}$ was applied but for the sporadic dermal exposure scenarios the $\text{AEL}_{\text{short term}}$. For the sporadic dermal exposure scenario the background inhalation exposure was added.

As described in the table below the respective risk for systemic effects results acceptable with exposure/AEL ratios for K-HDO far below 1.

Table 2.7.3.1 Risk for systemic effects from primary combined exposure from industrial use

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 for K-HDO [mg/kg bw day]	assessment factor = reference MOE	MOE	exposure / AEL
Inhalation	Tier 1: air concentration = saturation concentration; inhalation	0.001		0.001	AEL $_{\text{long term}}$ 0.021	300	5208	0.06
	Tier 2: air concentration = 1% of saturation concentration	0.00001		0.00001	AEL $_{\text{long term}}$ 0.021	300	520833	0.00
filling and loading + direct contact with treated panels (sporadic dermal)	Tier 1 inhalation + dermal without PPE	0.001	0.035	0.036	AEL $_{\text{short term}}$ 0.1	100	278	0.36
	Tier 2 inhalation + dermal with PPE	0.00001	0.0004	0.0004	AEL $_{\text{short term}}$ 0.1	100	25 000	0.0041

2.7.3.3 Risk for systemic effects from secondary exposure – adult processing treated wood

Processing of wood composites implies primarily cutting and handling. Secondary exposure due to processing of Xyligen 30F treated wood composites could occur to professionals or to the general public with a sporadic or a daily frequency. Consequently both toxicological reference values for the active substance K-HDO have to be considered, the AEL $_{\text{short term}}$ and the AEL $_{\text{long term.}}$

New measured dermal exposure data are provided by the applicant for this appliation for product authorisation. The data were taken into consideration within the tier 3 estimate. No exposure reduction by personal protective equippment was taken into account, since this is generally not adequate for risk assessment for general public. With the higher tier estimate the risk for systemic effects results acceptable also for repeated exposure from wood composite processing along the exposure assumptions.

Table 2.7.3.2 Risk for systemic effects from secondary exposure – adult processing treated wood

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 for K-HDO [mg/kg bw day]**	**assessment factor = reference MOE**	**MOE = NOAEL/ exposure**	**exposure / AEL**
Exposure during processing of wood	Inhalation and dermal tier 1 estimate	0.00044	0.032	0.032	AEL $_{\text{short term}}$ 0.1	100	308	0.32
					AEL $_{\text{long term}}$ 0.021	300	194	1.5
	Inhalation tier 1and dermal tier 3 estimate	0.00044	0.00012	0.00056	AEL $_{\text{short term}}$ 0.1	100	17 857	0.01
					AEL $_{\text{long term}}$ 0.021	300	11 250	0.03

2.7.3.4 Risk for systemic effects from secondary exposure – oral ingestion by infant chewing wood composite chips

Considering that the use of Xyligen 30F treated wood composites is intended for construction the exposure of infants by chewing treated wood composites should normally not happen. However for completing the assessment it was assumed that an infant chews a 4x4x1 cm treated wood composite and extracts all the K-HDO content (tier 1) or 10% (tier 2) of the K-HDO content. As described in the table below this assessments results critical since the exposure/ AEL $_{\text{short term}}$ ratio is far above 1 for tier 1 as well as tier 2 estimates. This confirms that the use of Xyligen 30F treated wood composites has to be restricted to applications where biocidal treatment is unavoidable (e.g. construction) but definitely excludes indoor applications allowing direct human contact.

Table 2.7.3.3 Risk for systemic effects from secondary exposure – oral ingestion by infant chewing wood composite chips

exposure scenario		estimated oral uptake [mg/kg bw day]	toxicity reference value for K-HDO [mg/kg bw day]	acceptable MOE = assessment factor	MOE = NOAEL/ exposure	exposure / AEL
Oral ingestion by infant chewing treated wood composite chips	Tier 1 100% of a.s. extracted from 4x4x1cm treated wood composite; 10 kg bw	4.6	AEL $_{\text{short term}}$ 0.1	100	2.17	46
	Tier 2 max 10% of a.s. extracted	0.46			21.7	4.6

2.7.3.5 Risk for systemic effects from secondary exposure – inhalation by adults and infants exposed to evaporated Xyligen 30F indoors

Xyligen 30F treated wood composites are applicable for use class 2 situations, which means a situation in which the 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 are within roof construction and outdoor under roof. Use within indoor living areas with direct human contact is not foreseen and should not be intended.

Application of Xyligen 30F for use class 3 situations (outdoor, not in contact with earth or water: boards for scaffolding that include an additional coating) the respiratory exposure may be considered small and below indoor exposure.

However for an estimation of any respiratory risk from Xyligen 30F treated wood composites the potential for chronic inhalation of K-HDO from treated wood in service was calculated. As with primary exposure this was calculated from the saturation concentration of K-HDO in air and as a second tier with ventilation leading to 1% of the saturation concentration .

The AEL $_{\text{long term}}$ was considered most appropriate for respective risk assessment for systemic effects from respiratory indoor exposure.

As shown in the table the AEL/exposure ratio is far below 1. Thus the situation of indoor exposure to evaporated K-HDO due to inappropriate use of Xyligen 30F treated wood composites bears an acceptable risk for adults as well as infants.

Table 2.7.3.5 Risk for systemic effects from secondary exposure – inhalation by adults and infants exposed to evaporated K-HDO indoors

exposure scenario		**estimated total uptake**	**toxicity reference value**	**acceptable MOE = assessment factor**	**MOE = NOAEL/ exposure**	**exposure / AEL**
		[mg/kg bw day]	[mg/kg bw day]			
Chronic inhalation of volatile residues indoors by adult	Tier 1 a.s. at saturation concentration, inhalation rate = 1.25 m^3/h, 18 hours exposure; 60 kg bw	0.003	AEL $_{\text{long term}}$		2100	0.14
			0.021	300		
	Tier 2 Ventilation leading to 1% of saturation concentration	0.00003	AEL $_{\text{long term}}$		210 000	0.00
			0.021	300		

Chronic inhalation of volatile residues indoors by infant	Tier 1 a.s. at saturation concentration, inhalation rate = 0.22 m^3/h, 18 hours exposure; 10 kg bw	0.0032	$\text{AEL}_{\text{long term}}$		2996	0.15
			0.021	300		
	Tier 2 Ventilation leading to 1% of saturation concentration	0.000032	$\text{AEL}_{\text{long term}}$		196 875	0.00
			0.021	300		

2.7.3.6 Summary of Human Risk Assessment for Xyligen 30F

The only ingredient of potential concern is the active substance Cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO). The risk assessment considered exposure scenarios related to the intended use. The respective risk for local effects on the skin, eye, gastrointestinal and respiratory tract can be considered acceptable on the basis of a qualitative assessment. The risk for systemic effects can be considered acceptable on the basis of a quantitative assessment. Xyligen 30 F treated wood composites must not be used for indoor living areas with potential direct contact, as the assessment for the exposure scenario “infant chewing wood composite” indicates an unacceptable risk.

2.8 Risk assessment for the environment

As the active substance stems from the same source as the active substance evaluated under Directive 98/8/EC for Annex I listing, and as the biocidal product corresponds to the representative biocidal product evaluated under Directive 98/8/EC for Annex I listing of K-HDO, please consult the final Competent Authority Report and the Assessment Report accompanying the Annex I entry.

Additionally submitted data/information on fate and behaviour, ecotoxicity and environmental exposure for the product or for the active substance compared to the Annex I CAR are assessed and summarised below.

2.8.1 Environmental effect assessment

2.8.1.1 Fate and distribution in the environment

Environmental fate and behaviour of potassium in the environment

Xyligen 30 F contains potassium as cation and Cyclohexylhydoxydiazene 1-oxide (HDO^-) as anion. During degradation of the HDO ion, potassium will remain in the environment.
Potassium is an alkali metal and occurs only as ionic salt in nature. As such, it is found dissolved in water and as part of many minerals (KCl, K_2SO_4 and silicates) in soil. Potassium ions are present in all plants and animal tissues. In plants, potassium is one of the three major nutrients. Different Potassium salts are used in fertilizers and plant nutrients and thus may increase the potassium content of plants.
The environmental fate of potassium was described in the SIDS initial assessment report of KCl[1]. K as an element is not subjected to further degradation processes in the environment. In water, the potassium ion is highly water soluble. In soil, transport/leaching of potassium and chloride is affected by the clay minerals (type and content), pH, and organic matter. Potassium is ubiquitous in the environment. The main exposure to K is the normal uptake via the environment (drinking water) but not by the wood preservative use.

Due to the high natural background concentration, the absence of a bioaccumulation potential and the low toxicity of potassium, no environmental risk assessment is considered necessary for the evaluation of potassium as cation in K-HDO. (Company statement Doc. III-B 7[2])

Read-across with Cu-HDO degradation studies

Read across strategy is proposed based on the following arguments:

- The HDO^- anion derived from Cu-HDO and K-HDO is structurally identical
- Cu-HDO and K-HDO showed similar distribution and excretion rates in toxicokinetic studies.

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[1] SIDS Initial Assessment Report, 2001, Potassium chloride, CAS No: 7447-40-7
[2] Company statement, 2011, Environmental fate and behaviour of potassium in the environment

- A comparison of the ecotoxicity data available for Cu-HDO, K-HDO, other copper compounds and copper in general show that the ecotoxicity of Cu-HDO is predominantly determined by the copper part of the molecule. Data are summarised in the following table:

Table 2.8.1.1.-1: Biodegradation, water/sediment

	Fish LC_{50} mg/L	Daphnia EC_{50} mg/L	Algae LC_{50} mg/L	Soil micro-organism NOEC mg/kg	Activated sludge EC_{50} mg/L
Cu-HDO	0.14 – 0.24	1.1	0.194	28.8	9
K-HDO	51.3	> 30	>30	>40.8	9
Copper	0.03 – 2.2	0.02 – 0.07	0.005 – 0.05	13.6*	2*

*Values from Copper Carbonate draft dossier

The inhibitory effects on activated sludge and soil microorganism of both substances are similar which suggests a similar behaviour of both substances in degradation tests. In the aquatic compartment the ecotoxicity of Cu-HDO is mainly based on the copper part of the substance whereas HDO has only a limited effect. Cu-HDO is considered as realistic worst case for the HDO molecules in degradation studies due to the higher inhibiting effects of copper.

- Cu-HDO and K-HDO show similar elimination behaviour in inherent degradation tests.
- The available ready biodegradation test of K-HDO (BOD- test, Haid, M., 1996, see Doc. II-A CAR on K-HDO) demonstrates 60% degradation after an incubation period of 30 days. The ready biodegradation test of Cu-HDO (OECD 301 D, Schwarz, closed bottle test, Doc. II-A CAR on Cu-HDO) demonstrates <10% degradation. Consequently Cu-HDO is considered as realistic worst case for degradation tests. (Company statements, Doc. III-B 7.1.2.2.2[3] and Doc. III-B 7.2.1[4])

Biodegradability in a water/sediment system:

Since K-HDO is not readily biodegradable and no water/sediment degradation study is available read across with a study performed with Cu-HDO is proposed.

The degradation of ^{14}C Cu-HDO in a water/sediment system was investigated in a study according to US-EPA test guideline section 162-4 (835.4300) before revision of the guideline in 2008. Therefore only one water/sediment system was tested (pond), the test duration was limited to 30 days and the temperature was maintained at 25°C. The applied test substance concentration was 2.2 mg ^{14}C Cu-HDO/L.

A DT_{50} value was calculated for the water phase with 2.4 days (biphasic kinetics, $r^2 = 0.988$). In the sediment phase the DT_{50} value was calculated with 20.3 days (first order kinetics, $r^2 = 0.910$). Both DT_{50} values represent dissipation of ^{14}C Cu-HDO, since partitioning to and from sediment and degradation are included. The DT_{50} value (degradation) for the total system was calculated with 14.5 days (first order kinetics, $r^2 = 0.966$).

Mineralisation was determined with 13.2% after 30 days of incubation. The corresponding DT_{50} value was calculated with 89.1 days (logistic kinetics, $r^2 = 0.981$). This value exceeds the limit of the observed data and is therefore considered beyond the range of reliable extrapolation.

Immediately after application 78.2% of the totally applied radioactivity (TAR) was found in the water phase. The radioactivity in water decreased to 5.5% TAR at day 30. The major component in the water phase was parent (75.4% TAR at day 0 and 2.8% TAR at day 30).

In the sediment phase 25.9% TAR was found at day 0 (16.6% TAR as extractable and 9.3% TAR as non-extractable residues).The extractable radioactivity content in the sediment increased to 45.2% at

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[3] Company statement, 2011, Water/sediment degradation study, Justification for non-submission of data

[4] Company statement, 2011, Aerobic degradation in soil, initial study, Justification for non-submission of data

day 10 and then decreased to 21.5% at day 30. Most of the extractable radioactivity was parent. The non-extractable residues continually increased up to 44% at day 30. The organo-soluble fraction was mainly parent containing only a small amoount of Cyclohexanone.
In the water phase as well as in the sediment phase a number of minor metabolites were observed. The only identifiable metabolite was Cyclohexanone which never exceeded 4.3% TAR (day 10) and declined over time. The only major metabolite found (13.2% TAR) was CO_2.

Two degradation pathways are proposed for Cu-HDO in water/sediment:

- Cu-HDO will either degrade to Cyclohexanone Oxime and further to Cyclohexanone which can be further transformed to 2-Cyclohexene-1-one or degraded to CO_2.
- Cu-HDO is degraded to 2-Cyclohexanol, then further to 2-Cyclohexen-1-ol and 2-Cyclohexen-1-one, which is then mineralised to CO_2.

Figure 2.8.1.1-1: Degradation pathway, water/sediment system

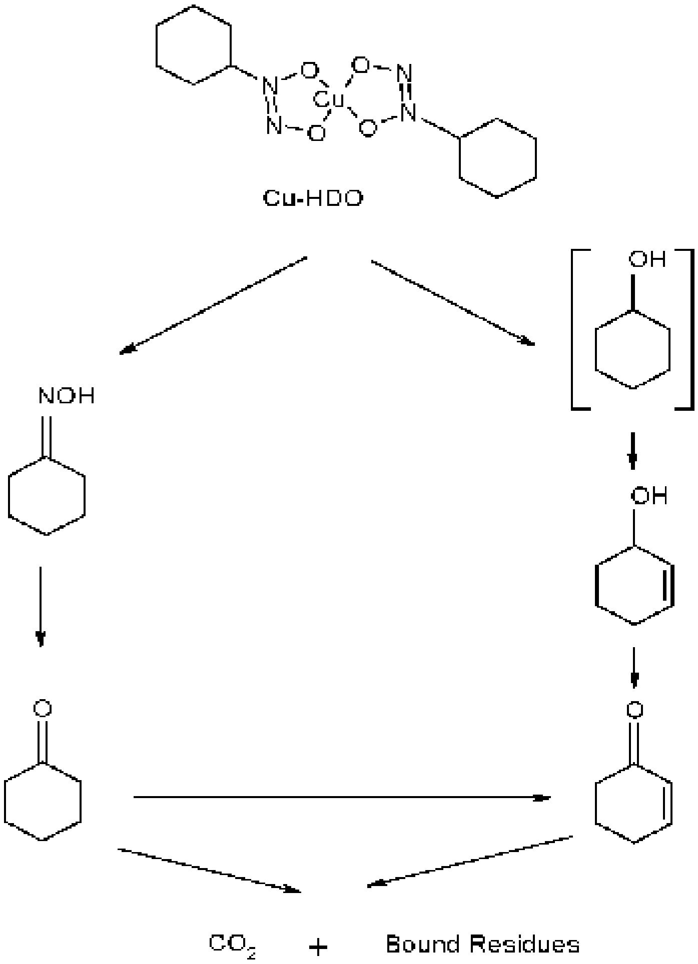

Table 2.8.1.1-2: Biodegradation, water/sediment

Guideline / Test method	**Test type**	**Test parameter**	**Inoculum**			**Additional substrate**	**Test substance concentration**	**Degradation**		**Reference**
			Type	**Concen-tration**	**Adaptation**			**Incubation period**	**Degree [%]**	
US-EPA Subdivision N, Section 162-4 (835.4300); Study performed before revision of guideline in October 2008	Aerobic water /sediment simulation test with ^{14}C Cu-HDO	Determination, identification and quantification of %TAR through LSC, GC-MS and HPLC.	Water and associated sediment from a pond located in Wabasha County, Minnesota.			-	2.2 mg ^{14}C Cu-HDO/L	30 d, dark conditions at 25°C	**DT_{50} dissipation, water phase 2.4 days (25°C);** biphasic kinetic (FOMC) DT_{50} dissipation sediment phase 20.3 days (25°C); first order kinetic (SFO) **DT_{50} degradation, total system 14.5 days (25°C); first order kinetic (SFO)** Mineralisation rate 13.2% after 30 days (25°C) Converted to standard conditions: **DT_{50} dissipation, water phase 6.8 days (12°C)** DT_{50} dissipation, sediment phase 57 days (12°C) **DT_{50} degradation, total system 41 days (12°C)** Mineralisation rate 13.2% after 84.9 days (12°C)	**Study B 7.1.2.2.2[5] and addendum[6]**

Biodegradability in soil:

Since K-HDO is not readily biodegradable and no soil degradation study is available read across with a study performed with Cu-HDO is proposed. The degradability of Cu-HDO in soil has been investigated in a laboratory test according to BBA guideline 4.1 (study B 7.2.1[7]). A DT_{50} value of 16 days and a DT_{90} value of 88 days were graphically determined. Since the DT_{90} value was <100 days no further testing was required according to the cited guideline. This study was considered sufficient for K-HDO.

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[5] Mahatam Singh, 2008, Aerobic Aquatic Metabolism of ^{14}C Cu-HDO, BASF Crop Protection, BASF RegDoc 2008/7007202, unpublished

[6] Mahatam Singh and Ralph L. Warren, 2010, Kinetic Evaluation – $^{14}CO_2$ Formation for Cu-HDO (Aerobic Aquatic Metabolism), Addendum to Aerobic Aquatic Metabolism of ^{14}C Cu-HDO, BASF Crop Protection BASF RegDoc 2010/7003160

[7] Wendelin Hettler, 1994, Examinations concerning the degradation of HDO in soil, Dr. Wolman GmbH, unpublished

However, this study was not accepted as key study for the Cu-HDO CAR by the TMIV09, since e.g. primary and ultimate degradation, identification and quantification of metabolites were not provided in the test report.
The applicant was asked to provide a test according to OECD test guideline 307 “Aerobic transformation in soil” for Cu-HDO. The study report will be due at the end of 2011.
Since revised PEC/PNEC values are expected to be <1 for most scenarios and it is further expected that the conclusions drawn on classification & labelling, persistence in soil and on PBT criteria will not be very likely influenced by the outcome of this study, it was agreed at TMI 11 that the process for even Cu-HDO under Directive 98/8/EC should not be stopped to await this study.

Conclusion:
At this point only the DT_{50} from Study B 7.2.1 is available for degradation in soil and is therefore used in this assessment. When the new Cu-HDO soil degradation study (OECD 307) will be available the results will have to be considered at date of renewal of the authorisation of Xyligen 30 F.

Table 2.8.1.1-3 Biodegradation, soil

Guideline / Test method	**Test type**	**Test parameter**	**Inoculum**			**Additional substrate**	**Test substance concentration**	**Degradation**		**Reference**
			Type	**Concen-tration**	**Adap-tation**			**Incubation period**	**Degree [%]**	
BBA 4.1 / Destination of pesticides in the ground - degradation, transformation and metabolism (BBA leaflet No. 36 and 56)	Degradation in soil / HDO content in soil		Slightly loamy sand Sand: 87.4% Silk: 9.1% Clay: 3.5% Organic Carbon: 0.7% pH: 6.2			-	5 mg HDO/kg soil (Wolmanit CX-S a formulation containing Cu-HDO was used as test-substance)	**DT_{50} ca. 16 days** DT_{90} ca. 88 days (graphically determined) **converted to standard conditions (12°C):** **DT_{50} = 35.6 days**		Study B 7.2.1

2.8.1.2 Effects on environmental organisms

Long term toxicity to fish

A fish juvenile growth test according to the OECD 215 guideline was carried out with K-HDO, conducted by the Laboratory for Wildlife and Fish Toxicology of Experimental Toxicology and Ecology, for a period of 28 days following the OECD guideline for Testing of Chemicals No. 215, adopted January 2000 "Fish, Juvenile Growth Test" (**study A 7.4.3.2**[8]**).**

Juvenile zebra fish (*Danio rerio*) were exposed to 0.033/0.11/0.33 /1.1 and 3.3 mg K-HDO/L. The test concentrations were selected on the basis of preliminary tests, which indicated mortality at 10.0 mg/L within test duration of 4 days. The study was performed under flow-through conditions with 5 concentrations of the test substance and a dilution water control. The temperature was maintained generally at 24°C, the dilution water was none-chlorinated drinking water obtained from the municipal water works mixed with deionised water to achieve a hardness of 1.4 mmol/L.

In the control and the concentration groups up to 0.33mg/L all fish survived until sacrifice. In the highest concentration group (3.3 mg/L), all fish died during the first day of exposure. In the concentration group 1.1 mg/L the survival rate was 30%. Mortalities were observed from days 1 – 14 after start of exposure.

In comparison to the control group the growth rate was statistically significantly reduced in the surviving animals of the concentration group 1.1mg/L after 14 days. No effects on the growth rate were detected in the lower concentration groups (nominal 0.033, 0.11 and 0.33mg/L).

Over the exposure period, no toxic signs and no abnormalities in the control and in the surviving fish of the concentration groups were observed.

In conclusion, the overall NOEC was 0.33 mg/L (nominal concentration) and 0.29 mg/L (based on the mean analytically determined concentrations) and the LOEC was 1.1 mg/L (nominal concentration) and 0.74 mg/L (based on the mean analytically determined concentrations).

The two highest concentrations the measured concentrations showed deviations of >20% of nominal. So the toxicity endpoints are given in mean analytically determined concentrations. Please see Table 2.8.1.2-1.

Table 2.8.1.2-1: Chronic toxicity to fish

Guideline /Test method	**Species**	**Endpoint /Type of test**	**Exposure**		**Results in mg/L mean measured**		**Remarks**
			Design	**Duration**	**NOEC**	**LOEC**	
OECD guideline 215	*Danio rerio*	Growth rate	Flow through	28 days	0.29	0.74	none

PNEC for aquatic organisms

The results from long-term tests are preferably used in the risk assessment. PNEC is to be determined on the basis of the chronic study with fish, because *Danio rerio* is the most sensitive species tested. The chronic toxicity to fish was determined to be mg 0.29 mg/L.

Since, long-term NOECs from at least three types of organisms (fish, daphnids and algae) are available, the NOEC is divided by the assessment factor of 10, according to the TGD on risk assessment.

à $\mathbf{PNEC_{water} = 0.029\ mg/L}$

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[8] Zoc S., 2005, N-Cyclohexyldiazeniumdioxy-potassium – Juvenile growth test in the zebra fish (*Danio rerio*) in a flow through system (28 days), Laboratory for Wildlife and Fish Toxicology of Experimental Toxicology and Ecology, BASF AG, Germany, Report No. 44F0069/015137, unpublished

PNEC for sediment organisms

For completeness the PNEC in sediment was calculated according to the equilibrium method theory derived from the $PNEC_{water}$ of K-HDO. (TGD on Risk assessment, Formula 70. RHO_{susp}=1150, $K_{susp\text{-}water}$ = 151 m^3/m^3).

à $PNEC_{sediment}$ = 3.8 x 10^{-3} mg a.i./kg ww

Toxicity to plants

Since no plant toxicity test with K-HDO is available read across with an acute plant toxicity study performed with Cu-HDO is proposed, assuming that the results of this study can be seen as a realistic worst case for K-HDO (company statement B 7.5.1.3[9]).

In the newly performed study according to OECD test-guideline 208 **(study B 7.5.1.3/02[10])** the short term toxicity of Cu-HDO to plants was investigated.

In this study Cu-HDO was tested at 5 different concentrations (62.5, 125, 250, 500 and 1000 mg/kg soil dry weight). Three different plant species (*Avena sativa, Brassica napus* and *Vicia sativa*) were tested.

The smallest NOEC found was 62.5 mg Cu-HDO/kg soil dry weight based on fresh matter in *Avena sativa* and in *Brassica napus*. Inhibitory effects up to 20% relative to the control were seen with all three species testes. EC_{50} values were only reached with *Brassica napus*. The smallest EC_{50} value was 161 mg/kg soil dry weight based on plant dry matter.

Conclusion:

The NOEC for plants = 62.5 mg Cu-HDO/kg soil dry weight. The EC_{50} for plants = 161 mg Cu-HDO/kg soil dry weight. Converting these results to standard soil the $NOEC_{plants}$ = 120.6 mg/kg soil dry weight, the $EC_{50plants}$ = 311.0 mg/kg soil dry weight.

Table 2.8.1.2-2: Toxicity to terrestrial organisms, toxicity to plants

Guideline / Test method	**Species**	**Endpoint / Type of test**	**Exposure**		**Results (mg/kg)**			**Re-marks**	**Reference**
			Design	**Duration**	**EC_{20}**	**EC_{50}**	**EC_{80}**		
OECD 208 / Terrestrial Plants, Growth Test and ISO 11269-2 Part 2 Effects of	*Avena sativa*	Emergence	Growth chamber test	15 days	>1000	>1000	>1000	—	**Study B 7.5.1.3/02**
		Dry matter			357	>1000	>1000		
		Fresh matter			309	>1000	>1000		
		Shoot length			>1000	>1000	>1000		
	Brassica	Emergence	Growth chamber	15 days	>1000	>1000	>1000	—	

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[9] Company Statement, 2011, Terrestrial plant toxicity , Justification for non-submission of data

[10] Jürgen Jatzek, 2006, Cu-HDO – Determination of the effect of chemicals on the emergence and growth of higher plants (oilseed rape (*Brassica napus*), oats (*Avena sativa*) and vetch (*Vicia sativa*)), BASF AG, Project No.: 65E0801/003018, unpublished

Chemicals on the Emergence and Growth of Higher Plants	*napus*	Dry matter	test		71	**161**	>250		
		Fresh matter			113	202	493		
		Shoot length			170	496	>1000		
	Vicia sativa	Emergence	Growth chamber test	15 days	>1000	>1000	>1000	—	
		Dry matter			>1000	>1000	>1000		
		Fresh matter			803	>1000	>1000		
		Shoot length			>1000	>1000	>1000		
					NOEC	**LOEC**			
	Avena sativa	Emergence	Growth chamber test	15 days	≥1000	>1000		—	
		Dry matter			250	500			
		Fresh matter			**62.5**	125			
		Shoot length			250	500			
	Brassica napus	Emergence	Growth chamber test	15 days	≥1000	>1000		—	
		Dry matter			125	250			
		Fresh matter			**62.5**	125			
		Shoot length			125	250			
	Vicia sativa	Emergence	Growth chamber test	15 days	≥1000	>1000		—	
		Dry matter			500	1000			
		Fresh matter			125	250			
		Shoot length			125	250			

<u>PNEC for terrestrial organisms</u>

Toxicity data for K-HDO are available for consumers (earthworm) and decomposers (micro-organisms). No toxicity data with plants have been performed so far with K-HDO, but an acute plant toxicity test with Cu-HDO was submitted for read across.

In the tests on **micro-organisms** no significant effects (C transformation -1.9% and N-transformation +4.4% inhibition) were observed up to the highest concentration tested. Therefore the NOEC for carbon transformation as well as for nitrogen turnover is ≥ 30 mg K-HDO/kg soil dry weight. The EC_{50} value for both endpoints is therefore >30 mg K-HDO/kg soil dry weight. Conversion of these results to standard soil leads to a **NOEC of ≥ 40.8 mg K-HDO/kg soil dry weight** and an **EC_{50} of >40.8 mg/kg K-HDO/kg soil dry weight** for both endpoints.

In the **earthworm** test no lethal effects were observed up to the highest concentration tested. The NOEC is =30 mg K-HDO/kg soil dry weight and the LC_{50} is >300 mg K-HDO/kg soil dry weight. Taking into account the high organic matter of the artificial soil (10%) conversion to standard soil leads to a **NOEC of 10.2 mg/kg soil dry weight** and a **LC_{50} of >102 mg K-HDO/kg soil dry weight**.

In the acute **plant** toxicity test performed with Cu-HDO the NOEC for plants = 62.5 mg Cu-HDO/kg soil dry weight the EC_{50} for plants = 161 mg Cu-HDO/kg soil dry weight. Converting these results to standard soil the NOEC = 120.6 mg/kg soil dry weight the EC_{50} = 311.0 mg/kg soil dry weight. Further conversion of these results based on molecular weight leads to a **NOEC value of 62.8 mg K-HDO/kg soil dry weight** and an **EC_{50} of 162.0 mg K-HDO/kg soil dry weight.**

According to the TGD the $PNEC_{soil}$ should be based on the lowest of the available short-term EC_{50} values. Based on the available EC_{50} values for all three trophic levels micro-organisms are the most sensitive species. The EC_{50} for micro-organisms is a > value and the same value as the NOEC. Dividing this EC_{50} by an assessment factor of 1000 would overestimate the risk.
It was therefore decided in TMI 07 to base the $PNEC_{soil}$ on the EC_{50} (=NOEC) micro-organisms and divide it by an AF of 100.

→ $PNEC_{soil}$ >0.408 mg a.i./kg soil dry weight

2.8.2 Risk characterisation for the environment

The biocidal product Xyligen 30 F is a wood protection product used in Use Class 2 and 3.
In the CAR accompanying the Annex I inclusion, for Use Class 2 environmental exposure during manufacturing, industrial application of the biocidal product Xyligen 30 F and service life of treated wood composites to the aquatic and terrestrial environment is assumed to be negligible.

Therefore in the following only environmental exposure for UC 3 is considered. According to the Intendes Use Xyligen 30 F is used for scaffolding boards only with an additional top coating which should prevent any leaching. The emission rates of K-HDO from freshly treated and old coated plywood boards are below the LOD of 0.05 mg/L. However, for realistic worst case considerations, the leaching rate was calculated by the limit of detection of the used analytical method.

PECs for 2 different buildings surraounded by scaffolding boards (realistic scenarios) were calculated (see Chapter 2.6.3):

A) House in the countryside (one-family house) and
B) Multi-storey building in the city

2.8.2.1 Aquatic compartment (incl. Sediment)

2.8.2.1.1 Sewage treatment plant

Direct release to STP is only considered relevant for buildings in the city.
The $PNEC_{micro\text{-}organisms}$ is 0.09 mg a.i./L (nominal) (see Doc. II-A CAR).

Table 2.8.2.1.1-1: PEC/PNEC ratios for STP micro-organisms for Xyligen 30 F

Exposure type	**PEC$_{STP}$ (mg a.s./L)**	**PEC/PNEC$_{STP}$**
	PNEC $_{micro-organisms}$= 0.09 mg a.i./L (nominal)	
Multi-storey building in the city, direct release to STP, EUSES	$0.9x10^{-4}$	$0.1x10^{-2}$

Conclusion:
PEC/PNEC value for STP is <1 for the calculated scenario, indicating an acceptable risk for aquatic micro-organisms. This result is confirmed by a reverse calculation (see Chapter 2.6.3), which indicates that the use of 10,000 m^2 of scaffolding boards still leads to a PEC/PNEC ratio <1. In the realistic scenario only 775 m² of scuffolding boards are needed.

2.8.2.1.2 Surface water

The PEC/PNEC ratios for the aquatic ecosystem have been calculated taking into account the PEC$_{SW}$ for a multi-storey building in the city (see Chapter 2.6.3) and using the PNEC for aquatic organisms (see Chapter 2.8.1.2).
à PNEC$_{water}$ =0.029 mg/L

To scaffold a house in the countryside will not lead to surface water contamination.

Table 2.8.2.1.2-1: PEC/PNEC ratios for aquatic organisms for Xyligen 30 F

Exposure type	**PEC$_{surface\ water}$ (mg a.s./L)**	**PEC/PNEC$_{SW}$**
	PNEC$_{aquatic\ organisms}$= 0.029 mg a.s./L	
Multi-storey building in the city, direct release to STP (realistic scenario)	0.00001	0.00034
Multi-storey building in the city, direct release to surface water (bypass STP) (realistic scenario)	0.00002	0.00069

PEC/PNEC ratios calculated for the emission scenarios are below the trigger of 1. Thus the intended use of Xyligen 30 F in scaffolding boards will not pose a risk to aquatic organisms.

PEC/PNEC value for surface water is <1 for the calculated scenario, indicating an acceptable risk for aquatic organisms.
This result is confirmed by a reverse calculation (see Chapter 2.6.3), which indicates that the use of 10000 m^2 of scaffolding boards still leads to a PEC/PNEC ratio for aquatic organisms <1. In the realistic scenario only 775 m² of scuffolding boards are needed.

Surface water used for drinking water

If surface water is intended for the abstraction of drinking water, the concentration calculation for K-HDO is 0.01 to 0.02 µg/L (see table 2.8.2.1.2-1). The scenarios meet the parametric value of 0.1 µg/L, according to Directive 98/83/EC.

2.8.2.1.3 Sediment dwelling organisms

The log P_{ow} of K-HDO is - 0.7 and the resulting BCF 0.134. So no toxicity study in sediment dwelling organisms was submitted and no sediment assessment is triggered.

The sediment risk assessment essentially is equal to the aquatic risk assessment as both $PEC_{sediment}$ and the $PNEC_{sediment}$ have been calculated by EqP from the $PEC_{local,water}$ and the $PNEC_{aquatic}$, respectively. The intended use of Xyligen 30 F in scaffolding boards will not pose a risk to benthic organisms.

2.8.2.1.4 Persistence in sediment

K-HDO is neither readily nor inherently biodegradable. No valid simulation tests are available for K-HDO. Therefore read across with a water/sediment degradation study performed with Cu-HDO was accepted.
In the sediment of a laboratory water/sediment system the DT_{50} value (dissipation) for Cu-HDO was calculated with 20.3 days at 25°C, corresponding to 30.3 days at 20°C, which is far below the threshold value of a DT_{50} >6 months at 20°C.
Non-extractable residues were formed at 44% TAR at day 30 (end of the study), threshold value >70% of the initial dose after 100 days.
Mineralisation rate was determined with 13.2% after 30 days of incubation, which is above the value of <5% in 100 days.

The consequences or effects on non-target organisms have been assessed in the risk assessment above and are acceptable.

Conclusion:
K-HDO is not persistent in sediment.

2.8.2.2 Terrestrial compartment

2.8.2.2.1 Soil

For the house in the country scenario direct release to soil is considered relevant, whereas only indirect release to soil via sludge application is considered relevant for buildings in the city with direct release to STP.

The $PNEC_{soil}$ is 0.408 mg a.s./kg soil d.w. (see Doc. II-A CAR).

Table 2.8.2.2.1-1: PEC/PNEC ratios for soil organisms for Xyligen 30 F

Exposure type	**PEC_{soil} (mg a.s./kg soil d.w.)**	**$PEC/PNEC_{soil}$**
	$PNEC_{soil\ organisms}$= 0.408 mg a.s./kg soil d.w.	
House in the countryside, direct release to soil	5.49×10^{-2}	0.13
Multi-storey building in the city, indirect release to soil, EUSES	2.58×10^{-3}	6.32×10^{-3}

Conclusion:
PEC/PNEC values for the soil compartment are <1 for the calculated scenarios, indicating an acceptable risk for soil organisms.
This result is confirmed by reverse calculations (see Chapter 2.6.3), which show that for the house in the country side the use of 500 m² of scuffolding boards still leads to a PEC/PNEC ratio <1, while in the realistic scenario only 72 m² of scaffolding boards are needed. For the multi-storey building in the city, where only indirect release to soil takes place, it is shown that the use of 10,000 m^2 of scaffolding boards still leads to a PEC/PNEC ratio <1, while in the corresponding realistic scenario only 775 m² of scuffolding boards are needed.

2.8.2.2.2 Persistence in soil

K-HDO is neither readily nor inherently biodegradable. No valid simulation tests are available for K-HDO. Therefore read across with a laboratory soil degradation study performed with Cu-HDO was accepted.
No field degradation studies are available for K-HDO.
In the above mentioned laboratory soil degradation study with Cu-HDO a DT_{50} value of 16 days at 22°C and a DT_{90} value of 88 days were calculated. Thereby the trigger value for non-inclusion of >6 months at 20°C is not met.
However, endpoints like the mineralization rate and the percentage of non extractable residues are not available in the test report and therefore the test was not accepted as a key study by the TM.
The applicant was asked to provide a test according to OECD test guideline 307 “Aerobic transformation in soil” for Cu-HDO. The study report will be due in the end of 2011.
It is expected that the results of this new study will not change the conclusion drawn on persistence in soil.
The consequences or effects on non-target soil organisms have been assessed in the risk assessment above and are acceptable.

Conclusion:
The available data indicate that K-HDO is not persistent in soil. When the new Cu-HDO soil degradation study (OECD 307) will be available the results will have to be considered at date of renewal of the authorisation of Xyligen 30 F.

2.8.2.2.3 Groundwater

For the Multi-storey building in the city with direct release to STP, the concentration in pore water of an agricultural soil after 10 continuous years of sludge application and averaged over 180 days is taken as an indication for potential groundwater concentrations. The $PEC_{groundwater}$ value is 0.02 µg a.s./L. This meets the parametric value of 0.1 µg/L, according to Directive 98/83/EC and therefore is acceptable.

It is assumed that scaffolding of a house in the countryside lead to direct emissions to soil and porewater adjacent to the house. The calculation of this scenario gives a $PEC_{porewater}$ for K-HDO of 0.46 µg/L. This is a realistic worst case assumption, neglecting transformation, adsorption and dilution in deeper soil layers. As the mean $K_{F,\ OC}^{ads}$ of K-HDO is 6006 L/kg, a translocation into deeper soil layers is not likely. Furthermore it was assumed that scaffolding boards are removed after a time period of 30 days. Additional to the short time frame and of exposure, no emission rates of K-HDO could be detected up to the LOD of 0.05 mg/L in the laboratory leaching test. Only for realistic worst case considerations, the leaching rate was calculated by the limit of detection of the used analytical method, but the real rate is lower. So the slight exceedance could be accepted and does not interfere with the parametric value of the authorised limit value of 0.1 µg/L for drinking water (European Council Directive 98/83/EC on the quality of water intended for human consumption). The use of Xyligen 30 F in scaffolding boards will not pose a risk to groundwater.

2.8.2.3 Non compartment specific effects relevant to the food chain (secondary poisoning)

Because of the BCF of K-HDO which is 0.134 there is no risk of accumulation.

2.8.2.4 PBT-Criteria

Persistence:
K-HDO is **neither readily nor inherently biodegradable**.
No valid simulation tests are available for K-HDO. Therefore read across with simulation studies performed with Cu-HDO was accepted.

In a **water/sediment** study, a DT_{50} for degradation of Cu-HDO in the total system was calculated with 14.5 days at 25°C (first order). Separate degradation rates for the water and the sediment phase were not calculated. Cu-HDO dissipates very fast from the water phase with a DT_{50} value (dissipation) of 2.4 days. Therefore degradation in the sediment phase was considered more relevant for the assessment of the P criterion than degradation in the water phase. The DT_{50} value for degradation (whole system) of 14.5 days was therefore used as a default value for degradation in the sediment phase. Conversion to standard European conditions (12°C) resulted in a DT_{50} value of 41 days.

P-criterion: $T_{1/2}$ >120 days in fresh sediment – DT_{50} =41 days (12°C) => not P

For the **soil** compartment a DT_{50} degradation value of 16 days at 22°C was determined for Cu-HDO in an aerobic degradation study in soil, corresponding to a DT_{50} value of 35.6 days at 12°C.

P-criterion: $T_{1/2}$ >120 days in soil – DT_{50} =35.6 days (12°C) => not P

Since the soil simulation test was not accepted the applicant was asked to provide a test according to OECD test guideline 307 “Aerobic transformation in soil” for Cu-HDO. The study report will be due in the end of 2011. It is expected that the outcome of this new study will not change the conclusions drawn on persistence. When the new Cu-HDO soil degradation study (OECD 307) will be available the results will have to be considered at date of renewal of the authorisation of Xyligen 30 F.

The available data indicate that K-HDO doesn’t meet the P-criterion.

Bioaccumulation:
K-HDO
BCF_{fish} = 0.134 (calculated)

K-HDO doesn’t meet the B-criterion.

Toxicity:
K-HDO
The chronic NOEC values for freshwater species are 0.29 mg/L for fish, 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 (see document II-A sections 3.5, 3.6, 3.7 and 3.8).

K-HDO doesn’t meet the T-criterion.

Conclusion:
According to the available data K-HDO doesn’t meet the PBT criteria and is therefore neither a vPvB, nor a PBT substance.

2.9 Measures to protect man, animals and the environment

The information submitted covering the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8 should be assessed and summarised here.

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire

Handling:
Application of Xyligen 30F is restricted to industrial fully automatic systems which practically exclude any exposure.

For the case of interventions necessary due to failure of the fully automatic system clean personal protective equipment, including a mask and daily new gloves, is highly essential. This since the product is a skin irritant and may cause severe damage of the eye.

P280 - Wear protective gloves/protective clothing/eye protection/face protection
P264 - Wash hands thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 – Avoid release to the environment

Storage:
Storage in original container tightly closed. Keep out of reach of children. Storage temperature: min. 15 °C (crystallization temperature: approx. 15 °C). Store away from acids.
Transport:
Dangerous Goods transport regulations have to be observed. Transport only in original container.
Fire fighting measures:
Suitable extinguishing media: Water, foam, carbon dioxide (CO_2), dry extinguishing media
Extinguishing media not to be used: —
Special protective equipment: —

8.2 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by the paragraph 8.3 (data set for active substance)

First aid measures:
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P362: Take off contaminated clothing and wash before reuse

P304 + 340, 312: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing; Call a POISON CENTER or doctor/physician if you feel unwell.

P305 + P351 + P338, P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing, Immediately call a POISON CENTER or doctor/physician

P301 + P330, P312: IF SWALLOWED: Rinse mouth, Call a POISON CENTER or doctor/physician if you feel unwell.

Environmental precautions: Do not discharge the product into drains or the environment

P391: Collect spillage

Methods for cleaning up: Sweep/shovel up. Soak up remainder with absorbent material

8.3 Procedures, if any, for cleaning application equipment

Methods for cleaning up: Application equipment can be cleaned by washing with water. However it has to be ensured that there is no release into the STP or environment.

8.4. Identity of relevant combustion products in cases of fire

Due to the chemical composition following combustion products are to be expected in case of the decomposition of K-HDO:

CO, CO_2, NO_X, HCN, H_2O

The identity of combustion products can also be deduced from the decomposition of Cu-HDO: The results of a fire protection test of pine wood treated with the Cu-HDO formulation Wolmanit CX-50 according to DIN 53 536 show that the concentration of the waste products CO, CO_2, HCN, NO_X correspond practically with the concentration of the burning of untreated timber.

8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration

P501: Dispose of contents/containers in accordance with local/regional/national/international regulations.

Recommendations: Dispose of by special means in accordance with local regulations e.g. suitable incineration

Contaminated packaging: After use and appropriate cleaning containers can be recycled or given back to the producer

8.6 Possibility of destruction or decontamination following release in or on the following: **(a) air** **(b) water, including drinking water** **(c) soil**	**(a) Air:** release into the air is not relevant; **(b) Water**: Release into water must be prevented. In case of accident, e.g. filtering with active charcoal **(c) Soil:** removal and dumping For large amounts, like spillage, pump-off product. For small amounts, pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder). Unwanted amounts of Xyligen 30 F can be destroyed by combustion in a licensed waste incinerator. Contaminated fluid shall be incinerated**.**
8.7 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms	Undesirable or unintended side-effects are not reported.
8.8 Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms	Not applicable.

3 Proposal for decision

3.1 Decision for granting an authorisation

As laid down in the Austrian authorisation decision directed to the Applicant.

3.2 Limits/restrictions of authorisation

Here the decision for granting an authorisation or not should be presented and in any case justified. The “specific provisions” and “elements to be taken into account by Member States when authorising products” from the assessment report(s) of the active substance(s) were duly taken into consideration. New data/information rendering these provisions and recommendations obsolete were be explicitly referenced.

No.	**(A) Limitations/restrictions of authorisation**	**(B) Original ”Elements to be taken into account by Member States when authorising products” as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC**	**(C) Elements maintained or changed with justification**
(1)	**The biocidal product may only be formulated using the active substance as specified in the Competent Authority Report accompanying the Annex I inclusion directive 2008/80/EC.** Justification: A change of source is considered being subject to an application for change of authorisation.	**a) Minimum degree of purity of the active substance** 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 f9) has to be considered.	Element maintained. See (A).
(2)	**See (1)**	**b) Nature and maximum content of certain impurities:** The nature and maximum content of the impurities have been specified.	Element maintained. See (A).
(3)	**Xyligen 30 F is restricted to the application as wood preservative (product type 8) for the protection of wood composites.** Justification: Other types of applications of Xyligen 30 F would require a different technology for which no human or environmental risk assessment was submitted; furthermore their	**c) Product type**: 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	Element maintained. See (A).

No.	(A) Limitations/restrictions of authorisation	(B) Original ”Elements to be taken into account by Member States when authorising products” as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC	(C) Elements maintained or changed with justification
	efficacy would have to be sufficiently demonstrated	environmental risk assessment was submitted; furthermore their efficacy would have to be sufficiently demonstrated	
(4)	**The application of Xyligen 30 F 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 application of K-HDO must not be cleaned and that appropriate personal protective equipment 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.	**d) Manner and area of use**: 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.	Change: 1) Assessment of production is out of the scope of biocidal product authorisation. 2) “including daily new gloves” is deleted: The applicant does not agree with the need for the use of daily new gloves. It is true that the exposure scenarios used for risk assessment were not based on the use of daily new gloves. The reason for proposing this requirement in the AR for KHDO was, that it is important to guarantee the defined margin of exposure and at the same time it is difficult to define the grade of dirtiness of gloves that

No.	(A) Limitations/restrictions of authorisation	(B) Original "Elements to be taken into account by Member States when authorising products" as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC	(C) Elements maintained or changed with justification
			results in an acceptable risk. However the issue may be considered to be within the responsibility of worker protection regulations and enforcement. Therefore we can agree to delete the wording "including new gloves". See (A).
(5)	**Designation of categories of users: industrial user** Justification: Other categories of users of Xyligen 30 F would require different human risk assessment which was not submitted	**e) Designation of categories of users:** industrial user	Element maintained. See (A).
(6)	**The accepted minimal and maximal application rates of K-HDO and Xyligen 30 F are as given in table 3.2.1. The application rate of 0.92% (w/w) Xyligen 30F/dry particle boards equals to 5.5 – 7.4 kg Xyligen 30F/ m³ dry particle boards with a density range of 600 to 800 kg/m³. These particle boards should be based predominately on softwood. A minimal application rate of 7.5 kg Xyligen 30F/m³ plywood, OSB and laminated veneer lumber (LVL) is recommended. The thickness of veneer layers in softwood-**	f1) 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/ m³ 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	Element maintained and amended. See (A).

No.	**(A) Limitations/restrictions of authorisation**	**(B) Original "Elements to be taken into account by Member States when authorising products" as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC**	**(C) Elements maintained or changed with justification**
	plywood is limited to 2.5 mm for outer veneer layers and 3.0 for inner veneer layers. For spruce/birch-plywood and pine/birch-plywood the veneer layers are limited to 1.8 mm and for LVL to 2.5 mm. Film coated plywood boards (phenolic surface coating) could be used for scaffolding in use class 3.1. Justification: The information is based on the submitted data. 0.3% (w/w) K-HDO/dry particle (corresponding to 1.6 - 2.2 kg K-HDO/ m³ 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/m3 as the maximum concentration of the intended uses was the basis for the risk assessment. For Plywood, Oriented strandboard (OSB) and Laminated Veneer Lumber (LVL), the minimum application rate was found to be 2.6 kg K-HDO/m^3, and the maximum application rate was 2.85 kg K-HDO/m^3. A lower concentration might result ineffective and a higher concentration might result in an unacceptable risk.	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.	
(7)	No limitation/restriction for Xyligen 30 F	f2) 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.	Not applicable: Additional data were submitted for Plywood, Oriented strandboard (OSB) and Laminated Veneer Lumber (LVL).

No.	(A) Limitations/restrictions of authorisation	(B) Original ”Elements to be taken into account by Member States when authorising products” as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC	(C) Elements maintained or changed with justification
		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.	
(8)	**Use of Xyligen 30 F in use class 3 is limited to use class 3.1, where only boards for scaffolding with coating, which is suitable to prevent leaching of the active substance into the environment, are allowed.** Justification: For use class 3 situations other than use for scaffolding boards with a water and abrasion resistant phenolic resin coating, which is suitable to prevent leaching of the active substance into the environment, no data were provided to show an acceptable efficacy and risk.	f3) 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.	Amended. See (A).
(9)	**Xyligen 30 F treated wood must not be used for use class 1 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	f4) 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	Amended. See (8) (A) and (9) (A).

No.	(A) Limitations/restrictions of authorisation	(B) Original "Elements to be taken into account by Member States when authorising products" as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC	(C) Elements maintained or changed with justification
	preservatives containing exclusively insecticides should be labelled for use class 1 applications.	sustainability policy and with the precautionary principle only wood preservatives containing exclusively insecticides should be labelled for use class 1 applications.	
(10)	**Xyligen 30 F treated wood composites must not be used for indoor living areas with potential of direct contact.** 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.	f5) K-HDO treated wood composites must not be used for indoor living areas with potential of direct contact 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.	Maintained. See (A).
(11)	**Xyligen 30 F 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 residues in food and feeding stuff was provided the use of Xyligen 30 F treated wood composites must exclude applications that may lead to contact with food and feeding stuff and contamination thereof.	f6) 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.	Maintained. See (A).
(12)	No limitation/restriction for Xyligen 30 F	f7) 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	Not applicable: New exposure data resulted in acceptable risk also for secondary exposure of

No.	(A) Limitations/restrictions of authorisation	(B) Original "Elements to be taken into account by Member States when authorising products" as described in the Assessment Report of K-HDO accompanying the Annex I inclusion directive 2008/80/EC	(C) Elements maintained or changed with justification
		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).	general public from processing of wood composites.
(13)	No limitation/restriction for Xyligen 30 F	f8) 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.	Not applicable: Exposure is not higher compared to assessment of active substance for Annex I inclusion.
(14)	No limitation/restriction for Xyligen 30 F	f9) 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	Element considered in biocidal product authorisation of Xyligen 30 F.
(15)	**See (8)**	f10) 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.	Element considered in biocidal product authorisation of Xyligen 30 F. See (8) (A).

3.2.1 Acceptable application rates

Table 3.2.1: Acceptable application rates

Use classes PT 08	**Formulation**		**Applied amount per treatment**			**Remarks**
	Type	**Conc. of a.s.**	**Method**	**kg as/m^3 wood-composite**		
				min.	**max.**	
2[1]	Xyligen 30 F	30%	Wood composites (e.g. Particleboards)	1.8	2.6	Preventive treatment
2[1]	Xyligen 30 F	30%	Wood composites (e.g. Plywood, Oriented strandboard (OSB) and Laminated Veneer Lumber (LVL))	2.25	2.85	Preventive treatment
3[2]	Xyligen 30 F	30 %	Coated wood composites[3]	2.25	2.85	Preventive treatment

[1] Use class 2: wood under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting

[2] In use class 3, Xyligen 30 F is only used for the treatment of boards for scaffolding and only with an additional coating. The coating prevents leaching into the environment.

[3] In use class 3.1 only film coated plywood boards used for scaffolding are permitted.

Annex:

1. **Summary of product characteristics**
2. **List of studies reviewed**
3. **Analytical methods residues – active substance**
4. **Toxicology and metabolism –active substance**
5. **Toxicology – biocidal product**
6. **Safety for professional operators**
7. **Safety for non-professional operators and the general public**
8. **Residue behaviour**

Annex 1: Summary of product characteristics

(a) Product trade name: Xyligen 30 F

(b) (i) Qualitative and quantitative information on the composition of the biocidal product

NB: This information is confidential and should not be disclosed to third parties

Active substance(s)				**Contents**				
Common name	**IUPAC name**	**CAS number**	**EC number**	**Concentration**	**Unit**[1]	**w/w (%)**	**Minimum purity (% w/w)**	**Same source as for Annex I inclusion**
Cyclohexylhydroxydiazene 1-oxide, potassium salt (short: K-HDO)	Cyclohexylhydroxydiazene 1-oxide, potassium salt	66603-10-9	not attributed	**300**	**g/kg**	**30**	**97.7**	☒ **yes** ☐ **no**

Co-formulants					**Contents**				
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Concentration**	**Unit**	**w/w (%)**	**Classification**	**Substance of concern**
water	water	solvent	7732-18-5	231-791-2	700	g/kg	70	---	☐ **yes** ☒ **no**

Sum	**1000.0**	**g/kg**	**100.0**

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[1] g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gramme or per litre).

(b) (ii) Is the product identical to the representative product, assessed for the purpose of the Annex I inclusion?

☒ **yes** ☐ **no** ☐ **unknown**

If not, briefly describe the difference.

(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

☐ **yes** ☒ **no**

If yes, does the product comply with Directive 2001/18/EC?

☐ **yes** ☐ **no**

A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

(c) Manufacturer(s) of the active substance(s) (name(s) and address(es) including location of plant(s))[2]

Name of the active substance: Cyclohexylhydroxydiazene 1-oxide, potassium salt (short: K-HDO)

Manufacturer

Company Name: Dr. Wolman GmbH
Address: Dr. Wolman-Str.31-33
City: Sinzheim Postal Code: 76547 Country: Germany
Telephone: +49-7221-800-0 Fax: +49-7221-80021 E-Mail:wendelin.hettler@wolman.de, rene.schwartz@wolman.de

Intra-Community VAT number or, for non EU companies, company registration number: no data requirement

Manufacturing site(s) (if different)

Company Name: BASF Aktiengesellschaft
Address: Carl-Bosch-Straße 38
City: Ludwigshafen Postal Code: 67056 Country: Germany
Telephone: (49) 621-60-0 Fax: --- E-Mail: ---

Intra-Community VAT number or, for non EU companies, company registration number: no data requirement

(d) Formulator(s) of the biocidal product (name(s) and address(es) including location of plant(s))[2]

Formulator

Company Name: Dr. Wolman GmbH
Address: Dr. Wolman-Str.31-33
City: Sinzheim Postal Code: 76547 Country: Germany
Telephone: +49-7221-800-0 Fax: +49-7221-80021 E-Mail: wendelin.hettler@wolman.de, rene.schwartz@wolman.de

Intra-Community VAT number or, for non EU companies, company registration number: no data requirement

Formulation site(s) (if different)

Company Name:
Address:
City: Postal Code: Country:
Telephone: Fax: E-Mail:

Intra-Community VAT number or, for non EU companies, company registration number:

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[2] All sites involved in the manufacturing process of each active substance and of the product must be listed.

Physical state and nature of the biocidal product:

(e) Type of formulation: solution

(f) Ready-to-use product: ☐no ☒ yes

Classification and labelling statements of the biocidal product:

(g) Product classification:

Hazard symbol: Xn
Indication of danger: harmful, irritant
Labelling symbol:

(h) Risk and Safety Phrases:

Risk Phrases:
R22 harmful if swallowed
R38 irritating to skin
R41 risk of serious damage to eyes

Safety phrases:
S 13, Keep away from food, drink and animal feeding stuffs
S26, In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S36/37/39, Wear suitable protective clothing, gloves and eye/face protection
S56, Dispose of this material and its container at hazardous or special waste collection point

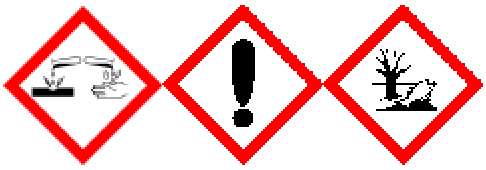
(i) Product classification according to Reg. 1272/2008/EC and 2nd ATP:

Acute Tox. 4
Skin Irrit. 2
Eye Damage 1
Aquatic chronic 2

(j) Hazard statement according to Reg. 1272/2008/EC and 2nd ATP:

H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H411: Toxic to aquatic life with long lasting effects

(k) pictograms



GHS 05/07/09

(l) Signal word: Danger

(m) Precautionary statements according to Reg. 1272/2008/EC and 2nd ATP:

Prevention:
P264 - Wash thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 – Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response:
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P362: Take off contaminated clothing and wash before reuse

P304 + 340, 312: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing; Call a POISON CENTER or doctor/physician if you feel unwell.

P305 + P351 + P338, P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing, Immediately call a POISON CENTER or doctor/physician

P301 + P330, P312: IF SWALLOWED: Rinse mouth, Call a POISON CENTER or doctor/physician if you feel unwell.

P391: Collect spillage

Disposal:
P501: Dispose of contents/containers in accordance with local/regional/national/international regulations

Intended uses and efficacy: Please see chapter 2.5 and 2.6 of this document.

Directions for use: Please see chapter 2.5 and 2.6 of this document as well as SPC.

Annex 2: List of studies reviewed

List of <u>new data</u>[3] submitted in support of the evaluation of the active substance

Section No	**Reference No**	**Author**	**Year**	**Title**	**Owner of data**	**Letter of Access**		**Data protection claimed**	
						Yes	**No**	**Yes**	**No**
A 7.4.3.2	A 7.4.3.2	Zoc, S.	2005	N-Cyclohexyldiazeniumdioxy-potassium – juvenile growth test in the zebra fish (Danio rerio) in a flow through system (28 days), Laboratory for Wildlife and Fish	Dr. Wolman GmbH		x	x	

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	**Reference No**	**Author**	**Year**	**Title**	**Owner of data**	**Letter of Access**		**Data protection claimed**	
						Yes	**No**	**Yes**	**No**
B 5.10.2/05	B 5.10.2/05	BAM	2000	Gutachterliche Stellungnahme… für das Holzschutzmittel Xyligen 30-F zur Verwendung in Sperrhölzern mit Laubholzanteilen	Dr. Wolman GmbH		x	x	
B 5.10.2/06	B 5.10.2/06	Möller R.	2009	Prüfung der Beständigkeit gegen holzzerstörende Basidiomyceten gemäß DIN V ENV 12038:2002-07	Dr. Wolman GmbH		x	x	

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[3] Data which have not been already submitted for the purpose of the Annex I inclusion.

Section No	**Reference No**	**Author**	**Year**	**Title**	**Owner of data**	**Letter of Access**		**Data protection claimed**	
						Yes	**No**	**Yes**	**No**
B 6.6/02	B 6.6/02	Seidel	2009	Surface sampling and analysis for residues of K-HDO from Xyligen treated particle and ply wood boards by the wipe test	Dr. Wolman GmbH		x	x	
B 7	B 7	Company Statement	2011	Environmental fate and behaviour of potassium in the environment, Justification for non-submission of data	Dr. Wolman GmbH		x		x
B 7.1	B 7.1/02	Wendelin Hettler	2008	Leaching behavior of Xyligen 30 F treated plywood boards exposed in UC 3, Dr. Wolman GmbH, Sinzheim. Germany	Dr. Wolman GmbH		x	x	
B 7.1.2.2.2	B 7.1.2.2.2	Company Statement	2011	Water/sediment degradation study, Justification for non-submission of data	Dr. Wolman GmbH		x		x
B 7.1.2.2.2	B 7.1.2.2.2	Mahatam Singh	2008	Aerobic Aquatic Metabolism of ^{14}C Cu-HDO	BASF SE	x		x	
B 7.1.2.2.2	B 7.1.2.2.2 Appendix 2	Mahatam Singh and Ralph L. Warren	2010	Kinetic Evaluation – $^{14}CO_2$ Formation for Cu-HDO (Aerobic Aquatic Metabolism), Addendum to Aerobic Aquatic Metabolism of ^{14}C Cu-HDO	BASF SE	x		x	
B 7.2.1	B 7.2.1	Company Statement	2011	Aerobic degradation in soil, initial study, Justification for non-submission of data	Dr. Wolman GmbH		x		x
B 7.2.1	B 7.2.1	Wendelin Hettler	1994	Examinations concerning the degradation of HDO in soil	Dr. Wolman GmbH		x	x	

Section No	**Reference No**	**Author**	**Year**	**Title**	**Owner of data**	**Letter of Access**		**Data protection claimed**	
						Yes	**No**	**Yes**	**No**
B 7.5.1.3	B 7.5.1.3	Company Statement	2011	Terrestrial plant toxicity , Justification for non-submission of data	Dr. Wolman GmbH		x		x
B 7.5.1.3 /	B 7.5.1.3 /02	Jürgen Jatzek	2006	Cu-HDO – Determination of the effect of chemicals on the emergence and growth of higher plants (oilseed rape(Brassica napus), oats (Avena sativa) and vetch (Vicia sativa))	BASF AG	x		x	

Annex 3: Analytical methods residues – active substance

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

Date: 01.07.2011

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products	Not attributed		
food of animal origin			
soil			
drinking water			
surface water			
air			
body fluids / tissues			

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
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 methods for the determination of K-HDO in food and feedstuffs are not required.					

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
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 methods for the determination of K-HDO in food and feedstuffs are not required.					

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
Wittenzellner 2004a, **A 4.2/01**	260	HPLC detection after extraction with methanol / extraction solution (ratio 1:4)	The LOQ is an estimation based on the LOD of 0.026mg/g as given in the study	Dr. Wolman GmbH

Methods for surface water

reference	matrix	LOQ (mg/l)	principle	comment	owner
Schmidt 1992, **A 4.1**	K-HDO as manufactured (30%w/w aqueous solution)	120	Colorimetric determination: Photometric detection at 425 nm after derivatisation with FeCl3	The study gives a LOD ≤ 4 mg/100mL. The LOQ given here is based on the asumption that LOQ = 3 * LOD	Dr. Wolman GmbH

Methods for drinking water

reference	matrix	LOQ (µg/l)	principle	comment	owner
No method suitable for the determination of K-HDO in drinking water has been submitted. (Justification: See chapter 3.2 point (4) and (8) of this document.)					

Methods for air

reference	LOQ (µg/m3)	principle	comment	owner
According to the Guidance on Data Requirements this analytical method is only required for volatile substances with a vapour pressure greater than 0.01 Pa.				

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
These analytical methods are only required where an active substance is classified as toxic or highly toxic. Although the purified active substance is classified toxic T, the active substance as manufactured (30%w/w aqueous solution) is only assigned Xn. Therefore, no methods concerning this end point have to be submitted, as long as the K-HDO content of the a.s. as manufactured is below 31 %w/w.					

Annex 4: Toxicology and metabolism –active substance

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

Threshold Limits and other Values for Human Health Risk Assessment

Date: 01.07.2011

Summary	Value	Study	SF
AEL long-term	0.021 mg/kg bw day	2-year study with structurally related Cu-HDO	300
AEL medium-term	0.034 mg/kg bw day	Developmental toxicity study in rabbit with structurally related Cu-HDO	300
AEL acute	0.1 mg/kg bw day	Developmental toxicity study in rabbit with structurally related Cu-HDO	100

Inhalative absorption	100%
Oral absorption	100%
Dermal absorption	8%

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	T; R25 Toxic; Toxic if swallowed. Xi; R38 Irritant; Irritating to skin. Xi; R41 Irritant; Risk of serious damage to eyes.
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox. 3, H301: Toxic if swallowed. Skin Irrit. 2 , H315: Causes skin irritation. Eye Damage 1, H318: Causes serious eye damage. STOT Rep. Exp. 2, H373: May cause damage to organs (gastrointestinal tract effects) through prolonged or repeated exposure.

Annex 5: Toxicology – biocidal product

Xyligen 30 F

Date: 01.07.2011

General information

Formulation Type	See Annex Chapter 1
Active substance(s) (incl. content)	See Annex Chapter 1
Category	Industrial user

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	= 452 mg/kg bw
Rat LD50 dermal (OECD 402)	> 5000 mg/kg bw
Rat LC50 inhalation (OECD 403)	> 26 mg/L
Skin irritation (OECD 404)	Irritant: erythema/edema average score ≥ 2, persistant till day 8
Eye irritation (OECD 405)	Serious eye damage: score 3 for cornea opacity and conjunctiva redness; score 4 for conjunctiva edema & bleeding; reversible after 8 days
Skin sensitisation (OECD 429; LLNA)	Not sensitizing: SI index < 3 (10-20-50%: 1.5-3.4-1.9)

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	Available just for active substance (purified K-HDO)
Toxicological data on active substance(s) (not tested with the preparation)	
Toxicological data on non-active substance(s) (not tested with the preparation)	
Further toxicological information	

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	See Annex Chapter 1
Regulation 1272/2008/EC	See Annex Chapter 1

Annex 6: Safety for professional operators

Xyligen 30 F

Date: 01.07.2011

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals

Component	**CAS**	**Potential Dermal Total [mg/day]**	**Potential Dermal Total [mg/kg/d]**	**Actual Dermal Total [mg/day]**	**Actual Dermal Total [mg/kg/d]**	**Inhalation Exposure [mg/m³]**	**Model**
K-HDO	66603-10-9	---	---	---	---	0.0057	calculation based on saturated concentration in air
K-HDO	66603-10-9	---	3.5 x 10^{-2}	---	4 x 10^{-4}	---	filling and loading: “model 7, Filling and loading” handling of treated panels: model “adult sanding wood”

Risk assessment

Component	**CAS**	**AEL [mg/kg/d]**	**Absorption**		**Inhal ext [mg/m^3]**			**Derm ext [mg/kg/d]**			**RCR total**
			inh	derm	Expo	RW	RCR	Expo	RW	RCR	
K-HDO	66603-10-9	0.1	100%	8%	0.0057	-	< 0.001	4 x 10^{-4}	-	0.004	0.004

The risk assessment for the substance(s) of concern has to be carried out in almost the same manner.

Annex 7: Safety for non-professional operators and the general public

Xyligen 30 F

Date: 01.07.2011

General information	
Formulation Type	See Annex Chapter 1
Active substance(s) (incl. content)	See Annex Chapter 1
Category	See Annex Chapter 1
Authorisation number	n.a.

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

Data base for exposure estimation

See chapter 2.6 of the PAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	not foreseen for non-professional operators and the general public
Secondary exposure, short term	sanding/processing of treated wood composites Oral ingestion by infant chewing wood composites chips
Secondary exposure, long term	sanding/processing of treated wood composites Inhalation by adult exposed to volatilized residues indoors Inhalation by infant exposed to volatilized residues indoors

Conclusion:

Exposure of non-professionals and the general public to the biocidal product containing Cyclohexylhydroxydiazene 1-oxide, potassium salt (short: K-HDO) as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Details for the exposure estimates: See product assessment report chapter 2.6.

Annex 8: Residue behaviour

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

Date: 01.07.2011

Intended Use (critical application): See chapter 2.6.1 and 2.6.2 of this document
Active substance(s): K-HDO
Formulation of biocidal product: Xyligen 30 F

The intended use descriptions of the K-HDO-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used for the preservation of wood that does not come in direct contact with food and feedstuff. No further data are required concerning the residue behaviour.