Bilag 2

Product Assessment Report

Sikkens Cetol HLS plus[BP]

Revised PAR October 2020
Addendum – minor change of the formulation – added October 2020
Revised PAR May and September 2015
Addendum – minor change of the formulation – added May and September 2015
Replaces PAR November 2011 and later updated December 6, 2012; see appendix 1 for details

Internal registration/file no:	MST-671-01749
Authorisation/Registration no:	782-2
Granting date/entry into force of authorisation/ registration:	25 November 2011
Expiry date of authorisation/ registration:	30th October 2025
Active ingredient:	Iodopropinyl butylcarbamate (IPBC)
Product type:	PT8

Biocidal product assessment report related to product authorisation under

Danish Ministry
of the Environment
Environmental
Protection Agency

Contents

General information about the product application

1.1 Applicant

Company Name:	Akzo Nobel Deco GmbH
Address:	Abteilung Joinery Vitalisstraße 198-226
City:	Köln
Postal Code:	D-50827
Country:	Germany
Telephone:	*See below*
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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mr. Ulrich Ditzen ; Ms. Kerstin Kokernak-Kniffel
Function:	Product Support Assistant
Address:	Abteilung Joinery Vitalisstraße 198-226
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1.2 Current authorisation holder[1]

There is no current authorisation for Sikkens Cetol HLS plus[BP] in Denmark.

[1] Applies only to existing authorisations

1.3 Proposed authorisation holder

Company Name:	Akzo Nobel Deco GmbH
Address:	Abteilung Joinery Vitalisstraße 198-226
City:	Köln
Postal Code:	D-50827
Country:	Germany
Telephone:	*See above*
Fax:	*See above*
E-mail address:	*See above*
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

1.4 Information about the product application

Application received:	June 23, 2011
Application reported complete:	February 4, 2011
Type of application:	Product authorisation
Further information:	Related to a frame formulation

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Sikkens Cetol HLS plus[BP]
Product type:	PT8
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see the confidential Bilag 3 to the letter of authorisation)):	0.7 % IPBC
Formulation type:	Liquid solvent-based wood preservative
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); **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):**	No No

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Use class 2 and 3. Application is done by brushing only (professionals and amateurs)
Target organisms:	Wood discolouring fungi (blue stain)
Category of users:	Amateur and professional use
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:	The product is applied at a rate of 200-250 ml/m^2 (186-233 g/m^2)
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Yes

1.5.3 Information on active substance(s)

Active substance chemical name:	IPBC
CAS No:	55406-53-6
EC No:	259-627-5
Purity (minimum, g/kg or g/l):	Min. 980 g/kg
Inclusion directive:	2008/79/EF of 28 July 2008
Date of inclusion:	1 July 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	
Company Name:	Troy Chemical Europe
Address:	Uiverlaan 12e, PO Box 132
City:	Maassluis
Postal Code:	3145
Country:	The Netherlands
Telephone:	+31 010 592-7494

1.5.4 Information on the substance(s) of concern

Substance chemical name	-
CAS No:	-
EC No :	-
Typical concentration:	-
Relevant toxicological/ecotoxicological information:	-

1.6 Documentation

1.6.1 Data submitted in relation to product application

See Annex 1 for complete references.

1.6.2 Access to documentation

The applicant has submitted the following letter of access:

Troy Corporation Inc. authorizes the use of the BPD dossier covering PT8 of Polyphase P100 (IPBC).

For further information on specific studies see dossier for application of the product.

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product contains the active substance IPBC (0.7% (w/w), purity: min. 980 g/kg).

The biocidal product is not identical to the representative product for Annex I inclusion.

The active substance is identical to the active substance listed in Annex I of Directive 98/8/EC.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification and labelling of the biocidal product

The current classification and labelling of Sikkens Cetol HLS plus[BP] according to Directive 67/548/EEC is shown here:

Symbols	-	
Category of danger	-	-
Risk phrases	-	-
Safety phrases	S2 S13 S24 S28	Keep out of the reach of children Keep away from food, drink and animal feedingstuffs Avoid contact with skin After contact with skin, wash immediately with plenty of water
Additional labelling	Contains IPBC, 2-Butanone oxime and Cobalt bis(2-ethyl hexanoate): May produce an allergic reaction	

2.2.2 Packaging of the biocidal product

The biocidal product is packed in 1 L, 2.5 L, 5 L, 10 L and 20 L round metal cans.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

Physico-chemical properties of the active substance:

A letter of access has been submitted for the active substance. An overview of the physico-chemical properties of the active substance can be found in the CAR.

A summary of the physical and chemical properties of Sikkens Cetol HLS plus[BP] is given in Table 2.3-1. The available data is evaluated and determined to be of sufficient quality and reliability for use in risk assessment (evaluation at the Document IIIB level).

Table 2.3-1: Physico-chemical properties of the biocidal product:

	Method	GLP (Y/N)	Results	Reference
Physical state and nature	Visual inspection	Y	Liquid suspension	Jungheim, 2010a
Colour	Visual inspection	Y	Ochre	Jungheim, 2010a
Odour	Olfactory inspection	Y	Slight chracateristic	Jungheim, 2010a
Explosive properties	EC method A.14	Y	The biocidal product is not explosive.	Keldenich, 2010
Oxidizing properties	EC method A.21	Y	The biocidal product has no oxidising properties.	Keldenich, 2010
Flash point	EC method A.9	Y	Flash point : 56,5 °C	Keldenich, 2010
Autoflammability	EC method A.15	Y	Auto ignition temperature: 395 °C	Keldenich, 2010
Other indications of flammability	EC method A.13	Y	The biocidal product has no pyrophoric properties.	Keldenich, 2010
Acidity / Alkalinity	CIPAC Method MT 75.3	Y	pH-value = 6.4 (undiluted) pH-value = 5.8 (1% in water) The acidity / alkalinity was not determined as the pH-value is between 4 and 10.	Jungheim, 2010a
Relative density / bulk density	EC method A.3	Y	Relative density: D420 = 0.930 The determination of the bulk density is not applicable because the biocidal product is liquid.	Jungheim, 2010b
Accelerated storage stability	CIPAC MT 46.3	Y	Storage condition: 40°C for 8 weeks. No significant changes of physicochemical properties were observed. IPBC content before storage at 40°C for 8 weeks: 0,713% IPBC content after storage at 40°C for 8 weeks: 0.700% Variation: 1.8% Before storage at 40°C for 8 weeks: pH-value = 6.4 (undiluted) pH-value = 5.8 (1% in water) After storage at 40°C for 8 weeks: pH-value = 6.2 (undiluted) pH-value = 5.8 (1% in water)	Jungheim, 2010a

	Method	GLP (Y/N)	Results	Reference
Low temperature stability	CIPAC MT 39.3	Y	The formulation is stable at 0°C for 7 days. No significant changes of physicochemical properties were observed. After 7 days at 0°C, no phase separation or sedimentation was observed.	Jungheim, 2010c
Reactivity towards container material	GIFAP Monograph No. 17	Y	At 8 weeks at 40°C: No significant interactions was observed At 6 months at 23°C ± 0.5°C No significant interactions was observed At 12 months at 23°C ± 0.5°C No significant interactions was observed At 24 months at 23°C ± 0.5°C No significant interactions was observed	Jungheim, 2010a Jungheim, 2011
Technical characteristics in dependence of the formulation type	–	–	The biocidal product has none of the properties mentioned in the TNsG on Data Requirements. Therefore no tests are necessary.	–
Compability with other products	–	–	Not applicable since the biocidal product will not be used with other products including other biocidal products.	–
Surface tension	–	Y	Not applicable due to its low water solubility.	–
Viscosity	OECD guideline 114	Y	Dynamic viscosity at 20°C: 265 – 332 mPa s The values of the viscosity vary depending on the shear rates, therefore the formulation is a non-Newtonian substance.	Jungheim, 2010b
Particle size distribution	–	–	Not applicable because the biocidal product is liquid.	–

2.3.2 Storage stability

The final results from the 2 year shelf-life study for the product are listed in Table 2.3-2-1.

Furthermore, a shelf-life of 3 years was applied for. It was informed to the company, as a result of a phys-chem workshop held March 12, 2013 in Arona, that it would be acceptable to prolong the shelf-life based on basis of a positive 2 year shelf-life GLP study as well as a non-GLP study after

2+ years including the active substance contents and certain physical parameters. The Danish CA concluded that the specific physical parameters which were most important to determine were pH, appearance and viscosity. The results from the 3 year test are included in table 2.3-3-2.

The shelf-life study has been carried out according to GIFAP Monograph No. 17, and conducted at 23°C ± 0.5°C. The active substance content has been analysed by a HPLC-UV method.
There has been observed no modification of appearance of the biocidal product during the storage period.

Table 2.3-2-1: Results from the shelf-life study.

Product	Active substance	Variation			
		Initial	6 mth	12 mth	24 mth
Sikkens Cetol HLS plus[BP]	IPBC	0.726 % -	0.723 % 0.4 %	0.712 % 1.9 %	0.677 % 6.7 %
	pH	6.7 (undiluted) 4.5 (1 % in water)	5.9-6.2 (undiluted) 5.4 (1 % in water)	6.1 (undiluted) 5.2 (1 % in water)	6.1 (undiluted) 5.2 (1 % in water)

References:
Initial, 6 months, 12 months data and 24 months data: Jungheim, 2012

2.3.3 Analytical methods

Analytical methods for the determination of IPBC residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance. Please refer to the dossier submitted for the active substance.

Analytical methods for the determination of active substance residues in/on food or feedstuffs are required if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or intended to be placed on, in or near soils in agricultural or horticultural use.

The active substance IPBC is not intended to be used in an above described manner. It is intended to be used as wood preservative. Its use is only recommended for the treatment of exterior constructions. The treatment of wood which is likely to come into direct contact with food or feedstuffs is excluded.

Since an exposure of IPBC to food and feedstuffs can be excluded when applied according to the recommended use, it is not necessary to submit an analytical method for the determination of active substance residues in/on food and feedstuffs.

2.3.3.1 Formulation analysis

A summary of the analytical method for the determination of the active substance IPBC in the biocidal product, presented under Document III B, Section 4.1, is given in Table 2.3-3.

Table 2.3-3: Validation parameters for analytical method

Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	Relative Standard deviation (RSD)	
IPBC	HPLC-UV	Fortification experiments were performed at three concentration levels: 80%, 100% and 120% of the concentration range of IPBC. At each level, two determinations were performed.	6 concentrations ranging from 80% to 120% of the debit content of the biocidal product. Each concentration was measured once. Correlation coefficient: 0.9998	No interferences were observed.	The mean recovery ranged from 100.4 to 101.4%. The overall mean recovery (n = 6) was 100.9% and the overall relative standard deviation (n = 6) was 0.51%.			Jungheim, 2010d

2.4 Risk assessment for Physico-chemical properties

The submitted physico-chemical data for the product has been evaluated according to 1999/45/EEC and directive 67/548/EEC.

The final results for Sikkens Cetol HLS plus[BP] indicate that the formulation is stable with regards to the active substance contents and the visual properties of the product at room temperature.
Furthermore, the other physico-chemical properties are considered acceptable.

Concerning long-term storage stability (shelf life), Denmark has up until now allowed a 15% deviation from the specified content for homogenous products containing less than 2.5% a.i., in line with the FAO recommendations. Due to EU harmonisation, the GIFAP monograph no. 17 may be followed in the future. However, this awaits a final agreement between the Member States. It should be mentioned that an EU harmonisation of long-term stability has been discussed very late in the process without a final decision. Therefore, we accept a 15% deviation in our evaluations of wood preservatives in progress.
It should also be noted that the results from the accelerated studies are overruled by the results from the long-term storage stability studies, if such studies are available.

The results for Sikkens Cetol HLS plus[BP] from the accelerated study shows that the degradation of IPBC after 8 weeks at 40ºC is 1.8 %, which is within the limit of 5 % degradation (according to OECD 113: Screening test for thermal stability and stability in air).

According to the 24 months results from the shelf-life study, IPBC has degraded by 6.7 %.

Conclusion:
On the basis of the final results from the long-term stability study, it can be concluded that the product is stable with regards to its contents of IPBC as well as the other physico-chemical properties, at least during the investigated period. A claim for 24 months shelf-life can therefore be accepted on the basis of the available stability data and the level of variation.

The overall conclusion of the risk-assessment for physico-chemical properties is that no unacceptable risk is identified after 24 months.

2.5 Effectiveness against target organisms

The efficacy assessment can be found in Bilag 4 to the letter of authorisation (Godkendelsesbrevet).

The recommended minimum and maximum retention is advised to be:
Minimum: 286 g product/m^2 which approximately correspond to 200 ml/m^2
Maximum: 233 g product/m^2 which approximately correspond to 250 ml/m^2

Sikkens Cetol HLS plus[BP] is recommended to be approved as a biocide product to protect against wood discolouring fungi in use class 2 and 3 for superficial application.

2.5.1 Dose / mode of action / known limitations / resistance

IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).

Due to the unspecific mode of action a development of resistance is neither to be expected nor has been ever observed.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Sikkens Cetol HLS plus[BP] contains 0.7% w/w of the biocidal active substance (a.s.) IPBC. It is used as wood preservative (BPD Product Type 8) for wood outdoors, which is not covered, not in direct contact with the ground or water (for use up to hazard class 3), and exposed to frequent weathering. This includes e.g. window frames and exterior doors (outside and inside) as well as facades, carports, pergola and balcony railings. Timber treatment is conducted by brushing only (professionals and amateurs).
The product is applied at a rate of 200 – 250 ml/m^2 (186-233 g/m^2), which results in a maximum total applied amount of 1631 mg IPBC/m^2 wood (233 g Sikkens Cetol HLS plus[BP] x 0.7 %).

2.6.2 Assessment of exposure to humans and the environment

Leaching studies have been submitted for the product. An evaluation of these and flux rates used for environmental risk assessment will be presented in Annex 4.

No new studies on human health have been submitted.

2.7 Risk assessment for human health

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 2 „Toxicology and metabolism" must be taken into consideration.

2.7.1.2 Toxicology of the substance(s) of concern

The product does not contain any 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.

2.7.1.4 Percutaneous absorption

Dermal absorption studies with the b.p. have not been conducted.

For solvent-based solutions containing 0.6% **IPBC**, a dermal absorption value of 30% has been set in the CAR by RMS Denmark. Therefore, a dermal absorption value of 30% will be assumed for the b.p. (0.7% IPBC).

2.7.1.5 Acute toxicity

No acute toxicity studies have been performed for the end-use product. However, in compliance with the provisions of Council Directive 1999/45/EEC on the classification, packaging and labelling of dangerous preparations, the acute toxicological profile of the end-use product can be deduced from available data of its main ingredients. According to this the product should not be classified for acute toxicity, corrosion or sensitisation.

The exact application of these classification methods can be found in Doc. IIIB, Section 6. The results of the classification are given in Table 2.7-1~~Table 2.7-1~~.

Table 2.7-1: Classification for acute health effects of Sikkens Cetol HLS plus[BP]

Endpoint	DPD classification
Acute oral toxicity	None

Acute dermal toxicity	None
Acute inhalation toxicity	Inhalation is not a relevant route of exposure
Skin irritation	None
Eye irritation	None
Skin sensitisation	None

IPBC is considered to be a skin sensitizer and proposal for classification has been submitted to ECHA. IPBC is present in the product at the concentration of 0.7%. Furthermore, the two substances 2-Butanone oxime and Cobalt bis(2-ethyl hexanoate) are classified as skin sensitizers. Each are however present in more than 0,1% but less than 1 % of the b.p. and does not contribute to the classification of the b.p. The product will therefore not be classified as a skin sensitizer. However the following sentence shall be stated on the label: Contains IPBC, 2-Butanone oxime and Cobalt bis(2-ethyl hexanoate): May produce an allergic reaction.

2.7.1.5.1 Other

The toxicological evaluation of the active ingredient, IPBC, has found no indication for a specific potential hazard for human health.

The b.p. contains 50% Naphta (petroleum), hydrotreated light (CAS No. 64742-47-8) that is classified Xn R65, R66. A compilation of the available data on this substance is summarised in Doc. IIIB6.5.

Since the b.p. contains about 50% solids, the viscosity is predictably too high to be classified as Xn, R65. The product will accordingly not be classified.

2.7.2 Exposure

The biocidal product contains 0.70% (w/w) IPBC (purity: min. 980 g/kg).

Exposure of professional and amateur users to the active substance while handling Sikkens Cetol HLS plus is estimated. The exposure pattern of amateur users will differ from that of professional users by a presumably lower daily use rate and annual use frequency. No PPE will be assumed to accommodate unprotected amateur users. Thus, no separate exposure assessment for amateurs was conducted.

Sikkens Cetol HLS plus is not intended or sold for the treatment of indoor housing areas with the exception of pre-treated window frames to be used indoors. An exposure assessment of residents inhaling volatile residues indoors has been included to estimate potential exposure from this source.

2.7.2.1 Identification of main paths of human exposure towards active substance from its use in the biocidal product

During and after the application of Sikkens Cetol HLS plus[BP], operator exposure could theoretically occur by dermal and inhalation routes.

However, the potential of exposure for operators through ingestion of the b.p. during brushing is negligible. The inhalation route is of minimal concern due to the low vapour pressure of the a.s. (4.5×10^{-3} Pa at 25°C) and the kind of application (no spray application).

Post-application exposure can occur too while handling treated wood and cleaning the brush.

Some secondary exposure is envisaged if contaminated work clothing is laundered at home; however, these exposure levels are insignificant compared to primary exposure.

Infants may be exposed via mouthing of treated wood chips.

Children and infants may be exposed via residues in playground structures.

Secondary exposure can arise if elements consisting of treated woods are sanded; the evolving dust can contain residual wood preservative which is inhaled together with the wood dust. This task can be performed by amateurs (acute scenario) or by professional craftsmen (chronic exposure).

Adults, children and infants may be exposed to volatile residues indoors from e.g. treated window frames.

The main routes of exposure are summarised in Table 2.7-2~~Table 2.7-2~~.

Formateret: Engelsk (USA)

Table 2.7-2: Summary of human exposure paths to IPBC

Exposure path	Professional use	General public	Via the environment
Inhalation	low	low	not relevant
Dermal	relevant	relevant	not relevant
Oral	not relevant	relevant for infants	not relevant

In Annex 3 „Human exposure assessment“, the results of the exposure calculations for the active substance and the substance of concern for the professional/ amateur user are laid out as well as for the indirect exposure.

2.7.2.1.1 Summary of primary exposure

The overall summary of primary systemic exposure is given in Table 2.7-3~~Table 2.7-3~~.

Formateret: Skrifttype: Ikke Fed

Table 2.7-3: Summary of primary exposure to IPBC

Scenario	Systemic dose [mg/kg bw/day]
Brush application	Inhalation: 0.00046 Dermal: 0.0611 **Total: 0.0616**
Cleaning the brush after use	**Dermal: 0.0214**
Total: application + cleaning	Inhalation: 0.00046 Dermal: 0.0825 **Total: 0.0830**

2.7.2.1.2 Summary of secondary exposure

The overall summary of secondary systemic exposure is given in Table 2.7-4~~Table 2.7-4~~.

Formateret: Skrifttype: Ikke Fed

Table 2.7-4: Summary of secondary exposure

Scenario	Systemic dose [mg/kg bw/day]
Acute: sanding of treated wood, amateur	Inhalation: 0.00006 Dermal: 0.0069 **Total: 0.0070**
Acute: chewing treated wood chip, infant	**Oral: 0.0261**
Chronic: sanding of treated wood, professional	Inhalation: 0.0003 Dermal: 0.0069 **Total: 0.0072**
Chronic: infant playing on playground structure out-doors and mouthing	Dermal: 0.0130 Oral: 0.0434 **Total: 0.0564**
Chronic, intermittent: adult laundering work clothes at home	**Dermal: 0.0013**
Chronic: Inhalation of volatile residues, indoors	**Inhalation:** Infant: 0.0012 Child: 0.0011 Adult: 0.0010

2.7.2.2 Exposure to residues in food

Not relevant, as contact with food is not predicted.

2.7.3 Risk Characterisation

With proper use in accordance with regulations 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.

2.7.3.1 Risk for Professional Users

Professional users involved in wood treatment by brushing are not exposed to critical doses of the a.s. With the assumption that the professional users use the recommended PPE, a sufficient margin of exposure is maintained in all reasonable scenarios (Table 2.7-5~~Table 2.7-5~~). All scenarios are assessed using the respective long-term AELs.

Table 2.7-5: Risk characterisation for primary exposure of professionals - long term

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Brush application	0.2	0.0616	31%	20	325
Cleaning the brush after use	0.2	0.0214	10.7%	20	870
Total: Application + cleaning	0.2	0.0830	42%	20	241

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.

2.7.3.2 Risk for non-professional users and the general public

Non-professional users are conservatively assumed to be exposed to the same doses of a.s. from the b.p. as are professionals. However, exposure of non-professionals is only on a few occasions per year, i.e., a short-term AEL applies to this scenario. Amateur users are not exposed to critical doses of the a.s. A sufficient margin of exposure is maintained in all reasonable scenarios (Table 2.7-6).

Table 2.7-7: Risk characterisation for primary exposure of amateurs - short term

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Brush application	0.35	0.0616	18%	35	568
Cleaning the brush after use	0.35	0.0214	6.1%	35	1636
Total: Application + cleaning	0.35	0.0830	23.7%	35	422

2.7.3.3 Indirect exposure as a result of use

An acute secondary exposure to a.s. can be anticipated for adult amateurs who work with treated wood (e.g., sanding) and for infants who may have oral contact with treated wood (e.g., chewing on a chip of treated wood). Children are not at risk for acute secondary exposure to wood preservatives.

Chronic secondary exposure is relevant for adults (professionals) who cut or sand treated wood as part of their occupation (e.g. carpenters).

Long-term, but intermittent (once per week) exposure can be envisaged for individuals laundering contaminated work clothing at home. Children may have repeated contact to treated wood, e.g., on playgrounds. For infants, oral absorption after mouthing is a possible route of exposure.

Inhalation of volatile residues indoors may be relevant for residents.

It can be concluded that the use of wood treated with Sikkens Cetol HLS plus[BP] does not pose an acute or chronic health risk for humans (Table 2.7-8~~Table 2.7-8~~).

Table 2.7-8: Risk characterisation for secondary exposure

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
amateur sanding	0.35	0.0070	2.0%	35	5,000
infant chewing wood	0.35	0.0261	7.5%	35	1,341
professional sand-ing	0.2	0.0072	3.6%	20	2,778
infant on play-ground	0.2	0.0564	28.2%	20	355
laundry	0.2	0.0013	0.7%	20	15,385
Inhalation of volatile residues, indoors. Infant	0.2	0.0012	0.51%	20	16949
Inhalation of volatile residues, indoors. Child	0.2	0.0011	0.57%	20	17544
Inhalation of volatile residues, indoors. Adult	0.2	0.0010	0.59%	20	19608

The direct exposure, exposure via the environment or to other residues resulting from the intended use is unlikely to cause any unacceptable acute or chronic risk to consumers (non-professionals, bystanders and residents). Regarding consumer health protection, there are no objections against the intended uses.

2.7.3.4 Combined exposure

Adults are the only subpopulation who may reasonably experience both primary and secondary exposure to the active substances in Sikkens Cetol HLS plus[BP]. The secondary exposure adds only negligible doses to the primary exposure, and it is furthermore unlikely that a professional would on the same day, cut and sand treated wood after having worked a whole day with application of wood preservatives.

2.7.3.5 Risk for consumers via residues

Not relevant, as contact with food is not predicted.

2.8 Risk assessment for the environment

2.8.1 Environmental classification

2.8.1.1 Environmental classification of the active substance

The environmental classification of the active substance is the following (based on Regulation 1272/2008/EC):

Substance	Env. classification	Effect concentration (mg/L)	Concentration of a.s. in the product (%)
IPBC	N; R50	0.053 (algae)	0.7

2.8.1.2 Environmental classification of the substance(s) of concern

The biocidal product does not contain any other substances with an environmental classification.

2.8.1.3 Environmental classification of the biocidal product

Calculations regarding the environmental classification have been performed for the product:

N; R50: 0.7/2.5= 0.28 <1

The resulting classification for the product is the following: None

2.8.2 Environmental exposure assessment

The environmental exposure assessment is based on the OECD series on emission scenario documents (OECD ESD) "Emission Scenario Document for Wood Preservatives (Part 1 and 2)" (OECD, 2003[2]). Where necessary the "Technical Guidance Document (TGD) for Risk Assessment" (European Commission, 2003) is also taken into consideration.

Emissions to the environment can occur during application and during the service life of the treated wood. Uses of Sikkens Cetol HLS plus[BP] as wood preservative include in-situ brushing by amateurs and professionals. For the envisaged fields of use for Sikkens Cetol HLS plus[BP] two main scenarios with the following sub-categories have been addressed (Table 2.8-1~~Table 2.8-1~~). The fence scenario has not been included as the timber cladded house is a worst case scenario for the terrestrial compartment.

Table 2.8-1: Relevant exposure scenarios for use of Sikkens Cetol HLS plus[BP]

Main exposure scenario	Subcategory
In-situ brush application by amateur and professional users	- Bridge over pond - Timber cladded house
In-service leaching from treated wood	- Bridge over pond - Timber cladded house

The product contains no substances of concern which will be included in the environmental risk assessment. Also there are no ecotoxicological tests with the product, the environmental risk assessment will therefore be based on the active substances within the product.

[2] OECD (2003): Emission Scenario Document for Wood Preservatives. OECD Series on Emission Scenario Documents No. 2 (Part 1-2). OECD, Environmental Directorate, Paris.

2.8.2.1 Assessment of service life

During the Arona Leaching Workshop in June 2005 (ECB, 2005)[3], it was agreed that a long-term assessment of in-service uses of wood should be carried out. For brushing treatments an assessment of cumulative leaching from treated wood in-service over a 5 year period was applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 5 years for the longer time period (TIME 2).

2.8.2.2 Leaching rates used for environmental risk assessment

A laboratory leaching study have been submitted, this is evaluated and leaching rates for the emission calculation have been calculated, see Annex 4.

For the risk assessment the leaching rates as shown in Table 2.8-2~~Table 2.8-2~~ are used.

Table 2.8-2: Leaching rates for Sikkens Cetol HLS plus[BP]

Active substance	Leaching rates (mg/m²/day)	
	TIME1 (30 days)	TIME2 (5 years)
IPBC	14.8	0.894

The leaching rate for TIME1 is calculated from the laboratory leaching study and corrected according to maximum application rate (233 g/m^2), and the rate for TIME2 is calculated based on 100% leaching of the maximum application amount in 5 years.

2.8.2.3 PEC calculations

The PECs for IPBC in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8. The PEC values presented are rounded values from EXCEL spread sheets. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

For the general assessment of the environmental fate and behaviour of the active substance refer to the Section on "Fate and Distribution in the Environment" in Doc. II-A of the CAR's.

In Table 2.8-3~~Table 2.8-3~~ substance specific input parameters used for the emission calculations are shown.

Table 2.8-3: Input parameters for the active substances

	IPBC
Half-life in the aquatic compartment (12°C)	3.1 hour (31.2 days)*
Half-life in the terrestrial compartment (12°C)	4.7 hour (9.5 days)*
Fraction staying in the water phase in the STP	0.97* IPBC is completely degraded to PBC in the STP
Koc	113.25 (198.1)*

* Values for PBC

PEC for surface water

Following the Emission Scenario Document for Product Type 8 (OECD 2003), $PEC_{surface\ water}$ for IPBC are calculated for different scenarios and applications. The potential PEC values for the sur-

[3] European Commission (2005): Report of the leaching workshop, 13-14 June 2005, EUR 21878EN, Nov. 2005.

face water depend on the input variables selected for each of the scenarios and the different emission pathways to surface waters.

For the in-situ treatments the proposed scenario in the ESD (OECD 2003) is a wooden bridge over a small pond (20 m^3 water volume). Calculations are conducted for a loss rate of 3 % (professionals) and 5 % (amateurs) caused by paint drops unintentionally reaching the water.

During the outdoor service life PECs for pre-treated (brushing) and in-situ treated wood are calculated. The target compartment is pond water (scenario "bridge over pond"). Using the OECD model "bridge over a small pond", the concentrations in pond water 30 days after application (TIME 1 = 30 days) and during the service life (TIME 2 = 5 years).

Further refinements of the initial PECs for surface water were done (only for direct emissions to the surface water) taking into account degradation of the active ingredients. According to OECD 2003 (Chapter 7: Removal processes in the receiving compartment, p.119) continuous releases into surface water can be calculated for either static or flowing water bodies. The assessment is calculated based on the static water body.

PEC for sediment

In the Danish CAR (2008) for IPBC the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the calculation of $PEC_{sediment}$ values is not considered necessary.

PEC for soil

According to the OECD ESD for Wood Preservatives (OECD 2003) PECs for IPBC in soil are calculated for different scenarios considering the user (professional or amateur), scale of operation, leaching period and the scenario-dependent soil volumes for emissions.

During the outdoor in-situ treatment initial PECs are calculated according to the emission models (OECD 2003) for brushing of a timber house, assuming 3 % (professionals) and 5 % (amateurs) emission of the applied product to the soil.

For the outdoor service life the OECD model 'timber house' is used.

A 50 cm distance and soil depth from the treated wood is defined as the receiving soil compartment in the model "timber house".

Further refinements of the initial PECs for soil were done taking into account degradation of the active ingredients (OECD 2003; page 118, equation 7.7 and 7.8).

PEC for groundwater

The environmental fate and behaviour of IPBC indicate that the substance is not expected to migrate to groundwater during outdoor service life of treated wood since it is rapidly degraded in soil (DT_{50} = 0.196 days (at 12°C)). Thus, the calculation of potential concentrations in groundwater is not considered relevant for the proposed used pattern (*cf.* Danish CAR, p.17).

PEC for atmosphere

IPBC will not be a subject of concern. IPBC has a low vapour pressure of 2.36 – 4.5 x 10^{-3} Pa at 25°C and a Henry's Law constant of 3.38 – 6.45 x 10^{-3} Pa×m³/mol. This indicates a very low risk of volatilisation. With regard to the fact that IPBC half-life in air is only about 15 hours, the substance is not considered persistent in air (as stated in the Danish CAR). Thus no assessment for a possible risk of the atmosphere (PEC_{air}) is conducted.

PEC for biota

According to the TGD (EC, 2003) the calculation of a possible risk to man via the food chain ($PECoral_{predator}$) should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log K_{ow} value >3.
IPBC reveals a log K_{ow} of 2.81 and PBC a log K_{ow} of 1.64 indicating that no risk for bioaccumulation of the substances to man via the food chain is given.

Calculated PEC values are summarised in Table 2.8-4~~Table 2.8-4~~ for IPBC. For IPBC either IPBC or PBC values are shown for the compartments surface water and soil, dependent on what value result in highest PEC/PNEC value. PEC values including degradation are shown in cases where there is a direct discharge to the compartment; this is shown by a symbol.

Table 2.8-4: Summary of PEC values (with and without degradation) for IPBC/PBC

IPBC/PBC	$PEC_{surface\ water}$ (µg/L)	PEC_{soil} (mg/kg_{wwt})
In-situ application (brushing)		
House (30 days) professional	-	0.0171*#
House (5 years) professional	-	2.26×10^{-59}*#
House (30 days) amatuer	-	0.0285*#
House (5 years) amatuer	-	3.77×10^{-59}*#
Bridge over pond (30 days) professional	6.93*#	-
Bridge over pond (5 years) professional	3.33×10^{-17}*#	-
Bridge over pond (30 days) amatuer	11.6*#	-
Bridge over pond (5 years) amatuer	1.00×10^{-16}*#	-
In-service		
House (30 days)	-	0.0234#
House (5 years)	-	1.43×10^{-3}#
Bridge over pond (30 days)	1.37#	-
Bridge over pond (5 years)	10.8*#	-
In-service and in-situ application (brushing)		
House (30 days) professional	-	0.0234#
House (5 years) professional	-	1.43×10^{-3}#
House (30 days) amateur	-	0.0234#
House (5 years) amateur	-	1.43×10^{-3}#
Bridge (30 days) professional	1.37#	-
Bridge (5 years) professional	10.8*#	-
Bridge (30 days) amateur	1.37#	-
Bridge (5 years) amateur	10.8*#	-

* Values for PBC
# Values including degradation

2.8.3 Environmental risk characterisation

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of Directive 98/8 involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. For this purpose Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative. The calculated PEC/PNEC ratios are provided for the aquatic and terrestrial compartment in the following.

If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment.

The PNEC values shown in Table 2.8-5~~Table 2.8-5~~ are used for the risk characterisation

Table 2.8-5: PNEC values used for risk characterisation

	IPBC/PBC
$PNEC_{STP}$ (µg/L)	440/-
$PNEC_{surface\ water}$ (µg/L)	0.5/41.3
$PNEC_{sediment}$ (mg/kg wwt)	Covered by surface water
$PNEC_{soil}$ (mg/kg wwt)	0.00434/0.149

Calculated PEC/PNEC values are summarised in Table 2.8-6~~Table 2.8-6~~ for IPBC.

Table 2.8-6: Summary of PEC/PNEC values (with and without degradation) for IPBC/PBC

IPBC/PBC	$PEC/PNEC_{surface\ water}$	$PEC/PNEC_{soil}$
In-situ application (brushing)		
House (30 days) professional	-	0.115*#
House (5 years) professional	-	1.52×10^{-58}*#
House (30 days) amatuer	-	0.191*#
House (5 years) amatuer	-	2.53×10^{-58}*#
Bridge over pond (30 days) professional	0.168*#	-
Bridge over pond (5 years) professional	8.06×10^{-19}*#	-
Bridge over pond (30 days) amatuer	0.280*#	-
Bridge over pond (5 years) amatuer	2.43×10^{-18}*#	-
In-service		
House (30 days)	-	**5.38#**
House (5 years)	-	0.329#
Bridge over pond (30 days)	**2.73#**	-
Bridge over pond (5 years)	0.262*#	-
In-service and in-situ application (brushing)		
House (30 days) professional	-	**5.38#**
House (5 years) professional	-	0.329#
House (30 days) amateur	-	**5.38#**
House (5 years) amateur	-	0.329#
Bridge (30 days) professional	**2.73#**	-
Bridge (5 years) professional	0.262*#	-
Bridge (30 days) amateur	**2.73#**	-
Bridge (5 years) amateur	0.262*#	-

* Values for PBC
# Values including degradation

For the house scenario environmental risk is identified for the soil compartment for the initial time period. This is however acceptable as the risk is reduced below the trigger value of 1 after 5 years. For the bridge over pond scenario a risk is identified for the aquatic compartment within the initial time period. However the risk is reduced below the trigger of 1 after 5 years.

As stated in section 2.8.1.3, the reported PNEC for the sediment is derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water.

Groundwater and air are not regarded as compartments of concern for this product with the proposed use patterns; also, there are no concerns of secondary poisoning (section 2.8.1.3).

Conclusion: The overall conclusion of the environmental risk assessment for the product Sikkens Cetol HLS plus[BP] applied by in-situ brushing is that no unacceptable risk is identified for secondary poisoning, sediment, soil, aquatic, air and groundwater compartments.

2.9 Measures to protect man, animals and the environment

Methods and precautions concerning handling and use

Due to the organic solvents content of the preparation:

Vapours are heavier than air and may spread along floors. Vapours may form explosive mixtures with air. Prevent the creation of flammable or explosive concentrations of vapours in air and avoid vapour concentrations higher than the occupational exposure limits. In addition, the product should only be used in areas from which all naked lights and other sources of ignition have been excluded. Electrical equipment should be protected to the appropriate standard.

Keep container tightly closed. Keep away from heat, sparks and flame. No sparking tools should be used.

Avoid contact with skin and eyes. Avoid the inhalation of dust, particulates, spray or mist arising from the application of this preparation. Avoid inhalation of dust from sanding.

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed.

Never use pressure to empty. Container is not a pressure vessel. Always keep in containers made from the same material as the original one. Comply with the health and safety at work laws.

Exposure controls: Provide adequate ventilation. Where reasonably practicable, this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and solvent vapours below the OEL, suitable respiratory protection must be worn.

Personal protection equipment:

Respiratory system: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. Dry sanding, flame cutting and/or welding of the dry paint film will give rise to dust and/or hazardous fumes. Wet sanding/flatting should be used wherever possible. If exposure cannot be avoided by the provision of local exhaust ventilation, suitable respiratory protective equipment should be used.

Skin and body: Personnel should wear antistatic clothing made of natural fibres or of high-temperature-resistant synthetic fibres.

Hands: For prolonged or repeated handling, use the following type of gloves: Recommended: nitrile rubber. Barrier creams may help to protect the exposed areas of the skin but should not be applied once exposure has occurred.
The user must check that the final choice of type of glove selected for handling this product is the most appropriate and takes into account the particular conditions of use, as included in the user's risk assessment.

Eyes: Use safety eyewear designed to protect against splash of liquids.

Methods and precautions concerning storage

Store in accordance with local regulations. Observe label precautions. Store in a dry, cool, well-ventilated area. Keep away from heat and direct sunlight.

Keep away from sources of ignition. Keep away from: oxidising agents, strong alkalis, strong acids.

No smoking. Prevent unauthorised access. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Methods and precautions concerning transport

Transport information: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

No marine pollutant.

This product is not regulated for carriage according to ADR/RID, IMDG, ICAO/IATA.

Methods and precautions concerning fire

Extinguishing media: Recommended: alcohol-resistant foam, CO_2, powders, water spray. Do not use water jet.

Special exposure hazards: Fire will produce dense black smoke. Exposure to decomposition products may cause a health hazard. Appropriate breathing apparatus may be required. Cool closed containers exposed to fire with water. Do not release runoff from fire to drains or watercourses.

Identity of relevant combustion products in cases of fire: Carbon monoxide, carbon dioxide, smoke, oxides of nitrogen.

Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available

First aid measures:

General: In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and seek medical advice.

Inhalation: Remove to fresh air. Keep person warm and at rest. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel.

Skin contact: Remove contaminated clothing and shoes. Wash skin thoroughly with soap and water or use recognised skin cleanser. Do not use solvents or thinners.

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open.

Ingestion: If swallowed, seek medical advice immediately and show the container or label. Keep person warm and at rest. Do not induce vomiting.

Emergency measures to protect the environment

Accidental release measures:

Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Environmental exposure controls: Do not allow to enter drains or watercourses. If the product contaminates lakes, rivers, or sewers, inform the appropriate authorities in accordance with local regulations.

Cleaning of equipment

Used equipment should be cleaned with white spirit.

Waste management

Do not allow to enter drains or watercourses. Dispose of according to all federal, state and local applicable regulations.
Hazardous waste: Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

3 Proposal for decision

3.1 Background for decision

Physico-chemical properties:
The overall conclusion of the risk-assessment for physico-chemical properties is that no unacceptable risk is identified after 24 months.
On the basis of the available stability data and the level of variation a claim for 24 months shelf-life can be accepted.

Efficacy evaluation:
Sikkens Cetol HLS plus[BP] is recommended to be approved as a biocide product to protect against wood discolouring fungi in use class 2 and 3 by superficial application at application rate 200-250 ml/m^2.

Human health assessment:
Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.
The direct exposure, exposure via the environment or to other residues resulting from the intended use is unlikely to cause any unacceptable acute or chronic risk to consumers (non-professionals, bystanders and residents). Regarding consumer health protection, there are no objections against the intended uses.

Environmental assessment:
The use of Sikkens Cetol HLS plus[BP] for professional and amateur wood preservation has been evaluated regarding its safety for the environment considering relevant emission scenarios. The overall conclusion is that Sikkens Cetol HLS plus[BP] does not pose an unacceptable risk to the environment.

3.2 Decision regarding Authorisation of the biocidal product

The Danish CA proposes the authorisation of the biocidal product Sikkens Cetol HLS plus[BP] as a wood preservative (PT 8) for use by brushing. The use rate is 200-250 mL/m², depending on application and retention capacity of the wood.

Identity of the Biocidal Product

The biocidal product under PT8 Wood preservatives Sikkens Cetol HLS plus[BP] contains 0.70% (w/w) IPBC.

Particular Conditions

Purity of the Active Substance

The active substance as manufactured shall have the following minimum purities:

IPBC: 980 g/kg

Product Type

PT8: Wood preservatives

Expiry Date of the Authorisation:

The authorisation of the product Sikkens Cetol HLS plus[BP] expires on 30 June 2020, which is the expiry date of Annex I listing of the active substances, i.e. that of IPBC.

Annex:

1. **List of studies reviewed**
2. **Toxicology and metabolism –active substance**
3. **Human exposure assessment**
4. **Leaching calculations**

Annex 1: List of studies reviewed

List of new data[4] submitted in support of the evaluation of the active substance

None

List of new data 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
B3.2(01) IIB, III 3.2 also filed B3.3(01) also filed B3.4(01)	1	Keldenich, H-P	2010	Determination of safety-relevant data of Sikkens Cetol HLS plus (Study no. 2010_00952).	Akzo Nobel Deco GmbH	☐	☒	☒	☐
B3.1(01) IIB, III 3.1 also filed B3.5(01) also filed B3.7(01)	2	Jungheim, R	2010a	Accelerated storage test of the wood preservation formulation Sikkens Cetol HLS plus (Study no. 2010_0054_03).	Akzo Nobel Deco GmbH	☐	☒	☒	☐
B3.6(01) IIB, III 3.6 also filed B3.10(01)	3	Jungheim, R	2010b	Physicochemical properties of the wood preservation formulation Sikkens Cetol HLS plus (Study no. 2010_0054_06).	Akzo Nobel Deco GmbH	☐	☒	☒	☐
B3.7(02) IIB, III 3.7	4	Jungheim, R	2010c	Low temperature storage test of the wood preservation formulation Sikkens Cetol HLS plus (Study no. 2010_0054_05).	Akzo Nobel Deco GmbH	☐	☒	☒	☐

4 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	
B3.7(03) IIB, III 3.7	5	Jungheim, R	2012	Long term stability test of the wood preservation formulation Sikkens Cetol HLS plus (Final report after 24 months) (Study no. 2010_0054_04).	Akzo Nobel Deco GmbH	☐	☒	☒	☐
B4.1	6	Jungheim, R	2010d	Validation of a HPLC method for the determination of IPBC in the wood preservation formulation Sikkens Cetol HLS plus (Study no. 2010_0054_01).	Akzo Nobel Deco GmbH	☐	☒	☒	☐
B5.10(01) IIB, V 5.10	7	Schumacher, P., Fennert, E.M.	2009	Determination of the protective effectiveness of SSH2993 PO-04 against blue stain according to EN152 Part 1(08/1989) after 4 weeks of artificial weathering	Akzo Nobel Industrial Deco GmbH	☐	☐	X	☐
B7.1(01) IIB, VII 7.1	8	Wegner, R.	2010a	Sikkens Cetol HLS Plus 2010 - Test Report No. 31/10/1404/02	Akzo Nobel Decorative Paints	☐	☐	X	☐

Annex 2: Toxicology and metabolism –active substance

Active Substance: IPBC

Threshold Limits and other Values for Human Health Risk Assessment

Summary			
	Value	Study	AF
AEL long-term	0.2 mg/kg bw/day	2 yr rat	100
AEL medium-term	0.35 mg/kg bw/day	90-day gavage rat	100
AEL acute	0.35 mg/kg bw/day	90-day gavage rat	100

Inhalative absorption	Default: 100%
Oral absorption	>90% based on urinary excretion (~57-71%) and exhaled air (~18-24%) within 72 hours.
Dermal absorption	1.6, 10, and 30% for solutions containing 17, 2.4 and 0.6% IPBC 100% default for solutions containing <0.5%-0.6% IPBC (based on *in vitro* human skin study with solvent based on model product)

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	T; R23 Xn; R22 Xi;R37-41 R43
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox 3 – H331 Acute Tox 4 – H302 Eye Dam 1 – H318 Skin Sens 1 - H317 STOT SE 3 – H335

Annex 3: Human exposure assessment

Sikkens Cetol HLS plus[BP]

Human exposure assessment calculations

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

To estimate dermal exposure, a **clothing penetration** for light clothing of **50%** (TNsG 2007 default) was assumed for non-professional users and as a worst case assumption for professional users.

Dermal absorption of **IPBC**, determined *in vitro* through human skin using a solvent-based formulation containing 0.6% IPBC, has been found to be **30%** (RMS DK, 2007a).

The default value for **body weight** of an exposed adult is assumed to be **60 kg** (ECETOC, 2001).

1 Primary exposure of professional or amateur users

1.1 Professional or amateur brushing - application

Mixing/loading

The b.p. is ready to use. Mixing/loading is therefore no relevant task.

Application

Exposure calculations are given according to TNsG 2007 (BEAT). Data for brush application of solvent-based wood preservatives to garden fences are available from the BEAT database.

This exposure study does not contain inhalation data. BEAT contains a smaller data set on "garden timber treatment" that also featured solvent-based products (Garrod A.N.I. *et al.* (2000). Potential exposure of amateurs (consumers) through painting wood preservative and antifoulant preparations. *Annals of Occupational Hygiene* **44** 421-426). The 75th percentile inhalation exposure from this data set will be used as surrogate, although inhalation exposure from brushing is going to be very low considering the lack of respirable aerosols and the low vapour pressure of the active substance.

The TNsG Excel database for human exposure gives a default value of 180 min for the duration of brushing of ready-to-use products.

The permeation of active substances through light clothing is 50% in the BEAT database, which is assumed as a worst case for professional users.

Cleaning

A post-application task which may lead to some degree of exposure is the cleaning of the brush. Cleaning of the equipment (brush) by professionals after the application event and lasts for no more than 15 min. It might result in some exposure to hands. The exposure during cleaning is not covered by any of the proposed TNsG models; therefore an internal calculation is provided. Exposure during cleaning is calculated in Section 1.2.

The scenarios and calculations for professional brushing and cleaning the brush by professional users explained above are applicable for amateurs as a worst case scenario. Amateurs, though, will not be exposed to the product for nearly the same duration as the professional.

Applied parameters for brushing:

Hands	**9.14 mg/min** (potential, 75th percentile, n=48)
Body	**1.12 mg/min** (potential, 75th percentile, n=48)
Clothing penetration	**50%** (light clothing, TNsG 2007)
Inhalation	**1.04 mg/m³** (potential, 75th percentile, n=15)
Inhalation rate	**1.25 m³/h** (default)
Duration	**180 min** (TNsG, Excel database)
Body weight	**60 kg** (default)

Estimated exposure during brushing: The estimated systemic exposure to IPBC is **0.0616 mg/kg bw/day** (Table A4-1).

Table A4-1: Exposure assessment for professional brush application

Brushing - solvent-based product	**IPBC**
active substance % (w/w)	0.70%
Potential body exposure	
Indicative value mg/min	1.12
Duration min	180
Potential dermal deposit mg	201.6
Clothing type	Light clothing
Clothing penetration %	50%
Actual dermal deposit [product] mg	100.8
Hand exposure	
Indicative value mg/min (potential)	9.14
Duration min	180
Hand deposit mg	1645.2
Mitigation by gloves	1
Actual hand deposit [product] mg	1645.2
Total dermal exposure	
Total dermal deposit [product] mg	1746
Active substance mg	12.22
Dermal absorption %	30.00%
Systemic exposure via dermal route mg	3.6666
Exposure by inhalation	
Indicative value mg/m³	1.04
Duration	180
Inhalation rate m^3/h	1.25
Mitigation by RPE (PF)	1
Inhaled [product] mg	3.90
Systemic exposure via inhalation route mg	0.027
Systemic exposure	
Total systemic exposure a.s. mg	3.6939
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.06157**

1.2 Professional or amateur brushing - cleaning the brush

Cleaning a brush used for solvent-based formulations may be done by repeated dipping and swaying it in a vessel containing commercial brush cleaner. A large brush might have a size of 10 × 10 × 2 cm, corresponding to a volume of 200 ml. Cleaning is assumed to be done in three steps, each time using fresh cleaner. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml, the required water volume would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush.

After each step the brush is assumed to be squeezed by the hand to get rid of as much liquid as possible. It is assumed that with this step 50% of the solution in the brush is released and may potentially

contaminate the hand. It is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which may absorb ca. 90% of the released liquid. Washing and squeezing may be done 3 times each at maximum. It is assumed that no mitigation by gloves occurs.

The estimated systemic exposure to IPBC is **0.0214 mg/kg bw/day** (Table A4-2).

The relevant parameters are summarised as follows:

Brush size : 10 × 10 × 2 cm (large brush, worst case)	200 ml
Volume of residual solution in brush (emptied by brushing)	1/8 of brush volume = 25 ml
Volume of each washing solution	at least 400 ml
Remaining residues in brush after each washing step	10%
Remaining residues in brush after each squeezing	50%
Penetration through cleaning rag during squeezing	50%
Density of product	0,930 g/ml
Body weight	60 kg

Table A4-1: Exposure assessment for professionals cleaning a brush after application

	IPBC	Explanation
active substance % (w/w)	0,70%	
Amount of a.s. in brush after use (mg)	162,75	25 mL x %a.s. x density
Residues in brush after 1st washing (mg)	16,275	10% of initial content
Squeezed out from a brush onto a cloth (mg)	8,14	50% of residual content
Cloth absorbs 50% of a.s.	4,07	50% of a.s. squeezed out
Potential dermal exposure 50% (mg)	4,07	50% of a.s. squeezed out
Amount of a.s. in the brush after 1st wash and squeezing (mg)	8,14	50% of a.s. remaining after wash
Residues in brush after 2nd washing (mg)	0,814	10% of a.s. content after 1st cycle
Squeezed out from a brush onto a cloth (mg)	0,407	50% of residual content
Cloth absorbs 50% of a.s. (mg)	0,203	50% of a.s. squeezed out
Potential dermal exposure 50% (mg)	0,203	50% of a.s. squeezed out
Amount of a.s. in the brush after 2nd wash and squeezing	0,407	50% of a.s. remaining after wash
Residues in brush after 3rd washing (mg)	0,041	10% of a.s. content after 2nd cycle
Squeezed out from a brush onto a cloth (mg)	0,020	50% of residual content
Cloth absorbs 50% of a.s. (mg)	0,010	50% of a.s. squeezed out
Potential dermal exposure 50% (mg)	0,010	50% of a.s. squeezed out
Total external dermal exposure (mg a.s.)	4,282	Sum of 3 cycles
Dermal absorption %	30,00%	
Systemic exposure mg day^{-1}	1,285	
Body weight kg	60	
Systemic dose mg kg^{-1} day^{-1}	**0,02141**	

2 Indirect exposure as a result of use of the active substance in biocidal product

2.1 Acute phase: Adult – sanding treated wood posts

Inhalation route

A person (non professional) is sanding the surface of treated wood posts (4 cm × 4 cm × 2.5 m, surface area of 4032 cm^2) for an outdoor play area. The active substances are in the outer 1 cm layer: The product is applied once at a rate of up to 250 ml/m^2 (at a relative b.p. density of about 0.930: 233 g/m^2). If 100% retention by the wood is assumed as the ultimate worst case, the wood can contain 233 g × 0.70% = 1.63 g IPBC /m^2 (0.163 mg/cm^2).

The IPBC concentration in the in outer 1-cm layer would be 0.163 mg/cm^3. The density of the wood is assumed 0.4 g/cm^3 (MOTA, TM08III). It is not possible to predict how much wood dust an operator would inhale while sanding wood treated with a wood preservative. As a surrogate parameter, it is assumed that the wood dust concentration does not exceed the applicable occupational exposure limits for dust at the workplace.

The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is 5 mg/m³ (Directive 1999/38/EC). The duration of a sanding task is an estimated one hour.

The results of this exposure estimate are given in Table A4-3. The **systemic exposure estimate** for IPBC is **5.69×10^{-5} mg/kg bw/day**.

Table A4-1: Exposure during sanding of treated wood

Sanding of treated wood	**IPBC**
active substance % (w/w)	0,70%
Concentration in wood	
Application rate [product] g/m²	233
Application rate [a.s.] g/m²	1,631
area of wood to be sanded surface area m²	0,4032
volume of outer layer (layer thickness 1 cm) cm³	3008
Amount in wood [a.s] g	0,658
Exposure by inhalation	
Concentration of in wood dust a.s mg/cm³	0,219
Wood dust concentration in air mg/m³	5
Exposure duration min	60
Inhalation rate m^3/h	1,25
Mitigation by RPE (PF)	1
Retention of a.s. in wood	100%
Density of wood g/cm³	0,40
Amount dust inhaled in 1 hour (cm³)	0,0156
Inhaled [a.s] mg	0,0034
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**5,69E-05**

Dermal route (hands – no gloves worn)

The highest concentration on the surface is 23.3 mg b.p./cm². The surface area of both palms of hands is 420 cm² and this is the assumed transfer coefficient per day, with a 100 % contamination as a worst case scenario. The transfer efficiency is 2% for rough sawn wood (TNsG 2007, p.102) and dermal uptake is 30% for IPBC.

The results of this exposure estimate are given in Table A4-4. The **systemic exposure estimate** for IPBC is **0.00685 mg/kg bw/day**.

Table A4-2: Exposure from dermal contact with treated wood

Touching of dry treated wood	
	IPBC
active substance % (w/w)	0,70%
Wood contamination	
Application rate [product] g/m²	233
Application rate [a.s.] mg/cm²	0,163
Percentage dislodgeable	2%
Dislodgeable residues mg a.s./cm²	0,00326
Hand exposure	
Transfer coefficient cm²/day	420
Hand deposit mg a.s./day	1,37
Dermal absorption %	30,00%
Systemic exposure via dermal route mg a.s.	0,4110
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00685**

2.2 Acute phase: Infant chewing treated wood chip

The relevant exposure route is oral. This is an incidental event and exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure. 100% retention of all active substances in the wood is assumed. It is assumed that all a.s. is bound in the outermost 1 cm of the timber volume and that this part is accessible to infants for chewing. It is further assumed that only a small fraction of the total preservative become released by chewing, as most of it is bound inside of the piece of wood. A reasonable assumption is that 10% may become released. A piece of the size of 16 cm^3 is chewed. Complete (100%) bioavailability is assumed for IPBC.

The results of this exposure estimate are given in Table A4-5. The **systemic exposure estimate** for IPBC is **0.0261 mg/kg bw/day**.

Table A4-1: Oral exposure via mouthing of treated wood

Mouthing of treated wood	
	IPBC
active substance % (w/w)	0,70%
Concentration in wood	
Application rate [product] g/m²	233
Application rate [a.s.] mg/cm²	0,163
Layer thickness cm	1,00
Retention of a.s. in wood	100%
Concentration in wood [a.s.] mg/cm³	0,163
Oral exposure	
Size of the wood chip cm³	16
Extraction of active substance when chewing	10%
Extraction from wood mg a.s./day	0,26
Oral absorption %	100%
Systemic exposure via oral route mg a.s.	0,261
Systemic exposure	
Body weight kg	10
Systemic exposure mg kg^{-1} day^{-1}	**0,0261**

2.3 Chronic phase: Adult – professional sanding

The acute sanding scenario is extrapolated to the chronic situation by assuming that the exposure time is 6 hours per day.

Inhalation route

The inhalation exposure is six times higher than for the one-hour task of an amateur (see Section 2.1, p.~~36~~36). Accordingly, the **systemic exposure estimate** for IPBC is **3.42×10^{-4} mg/kg bw/day**.

Dermal route (hands – no gloves worn)

The surface area of both palms of hands is 420 cm² and this is the assumed transfer coefficient per day. With this assumption, dermal exposure is independent of the daily exposure duration. The **systemic exposure estimate** for IPBC is **0.00685 mg/kg bw/day**, the same as for the acute scenario.

2.4 Chronic phase: Infant – playing on playground structure outdoors and mouthing

An infant (10 kg body weight) is playing on playground structure outdoors. The total body surface area of a 10-kg child is 0.467 m² (Bremmer & van Veen, 2000). The hands make up about 5.7% of that surface (US EPA, 2002). The palmar hand surface area is about 50% of the total hand surface. Thus, the exposed hand surface (= transfer coefficient) of a 2-yr old is 4670 cm² × 5.7% × 50% = 133 cm² (both hands) With a 100 % contamination, this is considered as a worst case scenario.. The concentra-

tion of a.s. at the wood surface is 0.163 mg IPBC /cm². The transfer efficiency is taken from the TNsG 2007 (page 102) as 2% for transfer of dried fluid from rough-sawn wood to skin.

In addition, the amount dislodged by the hands would be taken up by hand-to-mouth contact assuming an oral bioavailability of 100%.

The **systemic exposure estimate** for IPBC is **0.0564 mg/kg bw/day** (Table A4-6).

Table A4-1: Exposure of infants via skin and hand-to-mouth transfer

Touching of dry treated wood and mouthing	
	IPBC
active substance % (w/w)	0,70%
Wood contamination	
Application rate [product] g/m²	233
Application rate [a.s.] mg/cm²	0,163
Percentage dislodgeable	2%
Dislodgeable residues mg a.s./cm²	0,00326
Hand exposure	
Transfer coefficient cm²/day	133
Hand deposit mg a.s./day	0,43
Dermal absorption %	30,00%
Systemic exposure via dermal route mg a.s.	0,1302
Oral exposure	
Hand deposit mg a.s./day	0,43
Oral absorption %	100%
Systemic exposure via oral route mg a.s.	0,4338
Systemic exposure	
Total systemic exposure a.s. mg	0,5640
Body weight kg	10
Systemic exposure mg kg^{-1} day^{-1}	**0,05640**

2.5 Chronic (intermittent): Adults - cleaning work clothes at home

This scenario was adopted from the CAR for propiconazole (RMS FI, 2007). Persons at risk are adults. The relevant exposure route is dermal. Exposure duration is acute to short-term. An activity with the potential for some contamination is the laundering of contaminated work clothing (e.g. a coverall). Laundering is assumed to occur mechanically without any exposure risk to humans. Contact with effluent is unlikely to occur. The only likely exposure can occur during handling of the dirty clothing while preparing it for laundry. The exposure route is dermal (mainly to hands) and is dependent on the area concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to the human skin. For the following it is assumed, that the clothing to be washed is a coverall used by an industrial operator (considered to represent the worst case). The total surface of a medium size coverall was determined to be 22,700 cm². Body contamination (without hands and feet) was calculated to be 201.6 mg b.p. for the brushing scenario (see Section 1.1) are re-expressed as mg a.s./cm².

It is assumed that the coverall is washed after one working week, corresponding to 5 working days, and the total residues accumulate during this time and account for 5 times the daily deposits.

The transfer coefficient (TC) is determined by estimating how many times the coverall is touched with the hands. Assuming that this happens three times, twice with the inner side of both hands and once with the total hands surface, the TC would account for 1640 cm^2 (total surface of both hands = 820 cm^2). As another worst case assumption, 100% of the dislodgeable residues in the touched area are considered to be transferred to the skin. The results of the estimation are given in Table A4-7.

The **systemic exposure estimate** for IPBC is **0.0013 mg/kg bw/day**.

Table A4-7: Exposure during laundry of contaminated clothing

Laundry of contaminated clothing	
	IPBC
active substance % (w/w)	0.70%
Clothing contamination	
Actual dermal deposit [product] mg/day	201.6
Actual dermal deposit [a.s.] mg/day	1.41
Overall surface cm²	22,700
Surface concentration mg a.s./cm²/day	6.22E-05
No of working days before washing	5
Percentage dislodgeable	50%
Dislodgeable residues mg a.s./cm²	0.00016
Hand exposure	
Transfer coefficient cm²/day	1640
Hand deposit mg a.s./day	0.25
Dermal absorption %	30.00%
Systemic exposure via dermal route mg a.s.	0.0765
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.00127**

2.6 Adult, child and infant: Inhalation of volatised residues, indoors

Chronic exposure to wood preservatives may arise from indoor remedial treatment. Exposure through preserved window frames or joists is not considered to be relevant, because the frame or other wood

generally is coated and the wood preservative is sealed and cannot evaporate. IPBC furthermore has a low vapour pressure. Nevertheless, exposure by volatilised residues indoors was calculated.

The exposure of adults, children and infants to volatilised residues indoors was calculated under the provisions of the example calculation in the TNsG on Human exposure, 2002, part 3, (worked examples, page 50).
As a worst case, inhalation exposure was taken as 1% of the saturated vapour pressure/concentration (SVC; TNsG User guidance, 2002, page 52/53).

Assumptions:

- Adult: 60 kg bw, residential time 18 hours, inhaling 1.25 m^3 air/h (TNsG on HE, 2007, p 61)
- Child: 15 kg bw, residential time 18 hours, inhaling 0.35 m^3 air/h (TGD, page 274)
- Infant: 10 kg bw, residential time 18 hours, inhaling 0.24 m^3 air/h (TGD, page 274)
- Vapour pressure IPBC : 2.36 x 10^{-3} Pa (at 20°C)
- Molecular weight of IPBC : 281 g/mol
- 1 atmosphere (or 1 bar) is equivalent to 101325 Pa
- Molar volume of gas at room temperature: 24.1L

Results:

- Airborne concentration:
  IPBC : 2.36 x 10^{-3} Pa x 1%/101325 x 10^6 = 2.33 x 10^{-4} ppm (mL/m^3)
- SVC:
  IPBC: 2.33 x 10^{-4} ppm x 281 g/mol/24.1L = 2.72 x 10^{-3} mg/m^3
- Systemic dose:
  IPBC
  Adult: 2.72 x 10^{-3} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 1.02 x 10^{-3} mg/kg bw/day
  Child: 2.72 x 10^{-3} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 1.14 x 10^{-3} mg/kg bw/day
  Infant: 2.72 x 10^{-3} mg/m^3 x 0.24 m^3/h x 18 h/10 kg bw = 1.18 x 10^{-3} mg/kg bw/day

The exposure estimation revealed that chronic exposure to IPBC during residence time is negligible.

2.7 Exposure to residues in food

Not relevant, as contact with food is not predicted.

Annex 4: Leaching calculations

A laboratory leaching test (2 x 1 h) for Sikkens Cetol HLS plus[BP] was conducted in accordance with OECD Guidance No. 107 (2009) "Guidance on the estimation of emission from preservative treated wood to the environment: for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground".

The average daily leaching rate for each time interval was plotted versus the mean time of the time interval considered. A detailed description of this procedure can be found in Appendix 1 of the ESD for PT 8 (OECD, 2003).
For fitting the experimental FLUX(Δt)=*f*(t) curve a polynomial regression of second order was employed:

$$\log_{10}FLUX(t) = a + b*\log_{10}(t) + c*\log_{10}(t)^2$$

The fitted daily FLUX(t) corresponds to the quantity of the preservative compound leached per m^2 wood within the one day interval of the specific day t, while the experimental FLUX(Δt) represents the average quantities of IPBC leached per m^2 wood per day for a specific time interval Δt, and this time interval is more than one day. The trend lines with the corresponding regression equations and coefficients of variation can be found in Figure 1~~Figure 1~~.

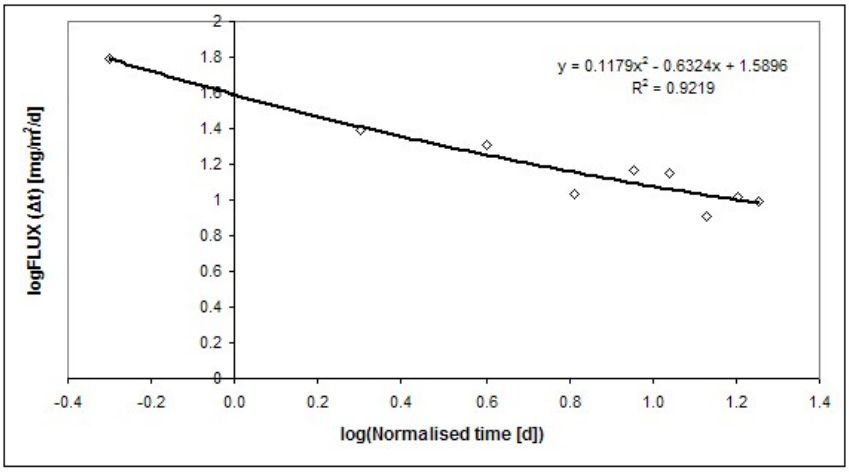

Figure 1 Fitted daily FLUX(Δt) of IPBC versus time

Once the parameter a, b and c are determined the experimental FLUX(t) = f(t) curve can be recalculated by using the following equation:

$$FLUX(t) = 10^{a} * t^{b} * t^{c\log t}$$

With the aid of the second equation leaching rates for the short–term risk assessment (TIME 1, 30 days) can be derived. For this purpose daily leaching rates for day 1 up to day 30 are summed up and divided by 30. With this approach the following short-term leaching rate is derived:

IPBC: 12.43 mg/m^2/day ((372.94 mg/m^2))/30 days)

A correction factor of 1.19 has to be adopted, because it is intended to apply higher amounts of the product than in the laboratory leaching study. The maximum intended applied amount of IPBC is 1631 mg/m^2 and in the leaching study only 1374 mg IPBC was applied per m^2. The following corrected short-term leaching rate is used as input parameter for the different exposure scenarios:

Day 1-30: used for short-term consideration (TIME 1: 30 days assessment)

IPBC: **14.753 mg/m^2/day** ((372.94 mg/m^2) / 30 days x 1.19)

Using this method for the long-term assessment leads to a predicted IPBC release exceeding the total applied amount. Therefore, according to the suggestions of the Arona Leaching Workshop in June 2005 (ECB, 2005), leaching rates for the long-term assessment are derived by dividing the total intended maximum applied amount of IPBC (1631 mg/m^2) by the respective service life time. For the long term risk assessment the following leaching rates were used:

Day 0-1825: used for long-term leaching TIME 2 (service life of 5 years)

IPBC: **0.8937 mg/m^2/day** ((1631 mg/m^2) / 1825 days)

3 Appendix 1 – Addendum to PAR May and September 2015

Minor and administrative change of the Product Family Sikkens Cetol HLS plus[BP]

Authorisation no: BPR-reg. nr. 695-7
Date: May and September 2015
R4BP3 case no: BC-DT017932-25
Asset number: DK-0012313-0000

3.1 Background

In the present application Akzo Nobel Deco GmbH applies for a minor change of the Product Family Sikkens Cetol HLS plus[BP].
The driers Cobalt preparation (CAS no. 136-52-7) and Strontium preparation (CAS no. 2457-02-5) are substituted by the less hazardous driers Manganese preparation (CAS no. 15956-58-8) and Zirconium preparation (CAS no. 22464-99-9). Furthermore the following changes have been made within the non-active substances: Removal of the stabilizer and encore of two UV-stabilizer and a catalyst. The total encore is lying in the range of less than 1% (documented by presenting of safety data sheets).
The modified product is called Product Family Sikkens Cetol HLS plus[BP] new hereafter in this document.
No changes were made with regard to conditions of use, conditions of storage and pack sizes.
For a comparison of the full composition of Product Family Sikkens Cetol HLS plus and the Product Family Sikkens Cetol HLS plus[BP] new, please refer to Appendix I/IA/IB of this document.

Description

According to Regulation IR 354/2013 a minor change of a product is a change, following which any change of the existing authorisation can be expected to be minor within the meaning of Article 3(1) (a, b) of Regulation (EU) No 528/2012, since the change of the product is not expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation. Such changes include the changes listed in the following, provided that the conditions therein are met:

List of allowed minor composition changes

Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product, where:

- The added or increased non active-substance is not a substance of concern.
- The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern.
- The physical-chemical properties and the shelf-life of the product are expected to remain the same.
- The risk and efficacy profile are expected to remain the same.
- A new quantitative risk assessment is not expected to be necessary

It is considered that all the criteria for a minor change listed above are fulfilled. This is explained in more detail in the following.

Impact of Family variations and addition of pigment on product properties

The tests referred to in the following were performed on the base products of Sikkens Cetol HLS Plus, i.e. the old tested formulation (SSH2993 PO-04) and the new tested formulations (BTC 077 and BTU 996) (find composition in Appendix I). For the original frame formulation of Sikkens Cetol HLS Plus it has previously been assessed that the variations

- will not adversely affect the physical-chemical properties.
- will not adversely affect the risk for human health because the products will be used the same way and none of the pigments have any properties known to be of concern for human health
- will not adversely affect the risk for the environment because none of the pigments have any properties known to be of concern for the environment
- will not adversely affect the classification because none of the pigments are known to be hazardous to human health or to the environment

At the same time it was assessed that the addition of up to 4% pigment in total has no adverse effect on the efficacy.
Since Product Family Sikkens Cetol HLS plus[BP] is identical to the original Sikkens Cetol HLS plus frame formulation, it is regarded that these arguments are also valid for Product Family Sikkens Cetol HLS plus[BP] as well.

1. Physical/chemical properties and storage stability

The determined data for the Sikkens Cetol HLS plus[BP] new and the previous results for Sikkens Cetol HLS plus show no significant differences.
Although for the viscosity measurements different parameters related to shear rates and temperatures were taken as a basis, the result is, that both recipes are a non-Newtonian substance and does not affect to consider classifications and/or labelling according DPD and CLP.
The observed densities are virtually identical.
The measured pH values during the tests for both recipes, are all within the range of 6,00 – 7,50.

A summary of some physical-chemical properties for the new recipe is given in Table 1 (for study see Appendix IVA).

Table 1

Study	Sikkens Cetol HLS plus new
Surface tension (25 C)	25.7 mN/m
Viscosity (40 C)	144 mPa*s
Density	0.9222 g/cm^3

The physical-chemical properties in Table 1 do not contribute to classification for Aspiration Toxicity (H304).

An accelerated storage stability test was performed with Sikkens Cetol HLS Plus[BP] new (see Appendix IIA/IIB). Compared to the previous results for Sikkens Cetol HLS Plus no significant impact on storage stability could be observed. In both tests the active substance was chemically and physically stable when stored at 35°C for twelve/eighteen weeks and at 40°C for eight weeks.
The results are shown in Table 2.
No adverse effects on storage and alteration of the active substance could be detected. The determined effects are all within the allowed tolerance.

Table 2

Study	Sikkens Cetol HLS plus	Sikkens Cetol HLS plus[BP] new	Status
Accelerated storage stability	Currenta study no. 2010/0054/03	DTI report no. 497196-4	Final
IPBC	0,713% / 0,700%	0,64% / 0,67 / 0,57%	
PH	6,4 / 6,2	7,41 / 6,78 / 6,06	

In conclusion the physical-chemical properties and the shelf-life (for 3 years) of the product are expected to remain the same.

It is assessed that the change of recipe for Product family Sikkens Cetol HLS plus[BP] will not adversely affect the physic-chemical properties and thereby the evaluation of the physico-chemical properties for Sikkens Cetol HLS plus[BP] new is applicable for the applied cobalt-free product family.

3. Classification and labelling

Through the described changes, resulting in the labelling only a change in the allergy phrase, here not naming of the cobalt-salt, see Table 3 below

Table 3

Labelling	Sikkens Cetol HLS plus	Product Family Sikkens Cetol HLS plus[BP] new
DPD, Directive 1999/45/EC	S2, S13, S24, S28 and allergy phrase (for IPBC, 2-Butanonoxime, Cobalt-salt)	S2, S13, S24, S28 and allergy phrase (for IPBC and 2-Butanonoxime)
CLP, Regulation 1272/2008/EC	P101, P102, P262, P312, P501 and allergy phrase (for IPBC, 2-Butanonoxime, Cobalt salt)	P101, P102, P262, P312, P501 and allergy phrase (for IPBC, 2-Butanonoxime)

4. Efficacy

According to EN599-1-2009 (*Durability of wood and wood-based products — Efficacy of preventive wood preservatives as determined by biological test*s), **Annex A -** *Guidance on re-testing after making variations in product formulation in the case of water-soluble preservatives* - **NO new biological testing is required** for changes involving substitution of any co-formulant by one which is chemically equivalent, from another supplier; In order to ensure

To avoid any discussion regarding existing chemically equivalence of the desired changes within the non-active-substance and in order to ensure that the biological efficacy is given, a new biological test according to EN 152 was performed (was passed).

However, additionally requirements in any case are as follows (Annex A, A2.5):
It should be confirmed:

a) that the penetration into wood is not adversely affected;
b) that the stability of the product is not adversely affected;
c) by chemical analysis, that the above changes do not alter the content of the active ingredients after storage at 40°C for 28 days.

a) Penetration
A test on effectiveness of a preservative treatment against blue stain according to EN 152 (2011) was performed with Sikkens Cetol HLS plus and the Sikkens Cetol HLS plus[BP] new. Reflecting the results of the tests (see appendix IIIA/IIIB), shown in Table 5, both products passed the requirement of the test in exceeding the limit penetration depth of 1.5 mm. Differences within the penetration depths, however are acceptable, are unavoidable because of different wood procurement (heard- and sapwood zones).

Table 4

Study	**Sikkens Cetol HLS plus**	**Sikkens Cetol HLS plus[BP] new**	**Status**
EN 152 – blue stain penetration depth			Final
	average 2,7 mm	average 1,5 mm	
	Report no. PB 32/0938/03	DTI report no. 497196-1	
	individual rating for blue stain on the surface: 0	individual rating for blue stain on the surface: 0	

In conclusion, the described changes under point 1.1, are not expected to have a negative impact on the effectiveness considering the results of the blue stain regarding blue stain on the surface (individual rating 0) and depth of the blue stain free zone (penetration).

It is assessed that the change of recipe for Product Family Sikkens Cetol HLS plus[BP] new will not adversely affect the efficacy. Two new efficacy tests were performed with two product variants containing 1.33 % w/w pigment and 1.51% w/w pigment including 0.69% w/w white pigment. It is assessed that the pigment content of at most to 4% will not have an adverse effect on the efficacy of the product and therefore the efficacy evaluation for Sikkens Cetol HLS plus[BP] new is applicable for the applied cobalt-free product family.
Only one limitation is necessary. In order to achieve an adequate penetration depth the titanium dioxide content should be limited to 0.5% at maximum (agreed with test institute DTI, Denmark).

b) Stability
The results of the accelerated storage stability test in Table 2 shows not adversely affected

c) Content of active ingredient
According to the current BPR guidelines, the results of the accelerated storage stability test in Table 2 show practically a stable content of active substance in the product.

4. Impact of minor change on human health and environmental risk assessment

Assuming a proper and safe use, in our view the minor change has no negative effects on human health and the environment. The previously existing risk assessment for human health and environmental, can be transferred to the new formulation and it is not necessary to create a new quantitative risk assessment.

In terms of the health of the user, has specifically the exchange of the cobalt-drier, set a positive effect in the risk profile of the product.

Therefore products associated with the Sikkens Cetol HLS plus[BP] cobalt-free product family will be used in the same way as the associated products of the former product family Sikkens Cetol HLS plus[BP].

Based on information from SDS and Annex VI to Regulation (EC) No 1272/2008 none of the pigments will be of concern for the human health within the specified concentration limits.
The risk assessment and characterisation of the cobalt-free product family for Sikkens Cetol HLS plus[BP] is therefore the same as for the former Sikkens Cetol HLS plus[BP] product family.

Based on information from SDS and Annex VI to Regulation (EC) No 1272/2008 none of the pigments has any properties known to be of concern for the environment which does not change the classification.
The risk assessment and characterisation of the cobalt-free product family for Sikkens Cetol HLS plus[BP] is therefore the same as for the former Sikkens Cetol HLS plus[BP] product family.

Overall conclusion

Based on the argumentation above, the described changes (minor change) under point 1.1 in the Product Family Sikkens Cetol HLS plus[BP] can be accepted.

List of Appendixes:

Appendix number	Year	Title	Data protection claimed	owner
I	09/2015	Recipe comparison of the Product Family Sikkens Cetol HLS plus[BP] (previously and newly) and the test formulations	confidential	AkzoNobel Decorative Coatings B.V.
IIA	09/2010	Currenta study no. 2010/0054/03 (Accelerated storage test)	confidential	AkzoNobel Decorative Coatings B.V.

IIB	02/2014	DTI report no. 497196-4 (Accelerated storage test)	confidential	Akzo Nobel Decorative Coatings AB
IIIA	06/2009	MPA Test report no. 32/09/9238/03	confidential	Akzo Nobel Decorative Paints
IIIB	08/2013	DTI report no. 497196-1	confidential	Akzo Nobel Decorative Coatings AB
IVA	11/2014	Currenta study, LIMS no. 2014-045502	confidential	Akzo Nobel Decorative Coatings AB

4 Appendix 2 – Addendum to PAR October 2020

Minor change of the Product Family Sikkens Cetol HLS plus[BP]

Authorisation no: BPR-reg. nr. 782-2
Date: October 2020
R4BP3 case no: BC-FG058184-47
Asset number: DK-0012313-0000

4.1 Background

In the present Application Akzo Nobel Decorative Coating B.V applies for a minor change of the Product Family Sikkens Cetol HLS plus[BP].
The anti-skinning agent 2-butanone oxime (CAS no. 96-29-7) is substituted by a less hazardous anti-skinning agent in the same concentration (less than 1%). Please see confidential Annex for further information, including confidential composition.
According to the proposed change, as drafted in 15th ATP, 2-butanone oxime will be reclassified as Carcinogen 1B; (H350) "Will cause cancer". This classification will restrict the usage of the biocidal product to professional users only. To ensure that the biocidal product family has a prolonged future in non-professional markets, the applicant applied for a minor change of the Product Family.

4.2 Description

According to Regulation (EU) 354/2013 a minor change of a product is a change, following which any change of the existing authorization can be expected to be minor within the meaning of Article 3(1) (ab) of Regulation (EU) No 528/2012, since the change of the product is not expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation. Such changes include the changes listed in the following, provided that the conditions therein are met:
List of allowed minor composition changes
Increase or reduction, addition or replacement of a non-active substance intentionally incorporated in the product, where:

- The added or increased non-active-substance is not a substance of concern.
- The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern.
- The physical-chemical properties and the shelf-life of the product are expected to remain the same
- The risk and efficacy profile are expected to remain the same
- A new quantitative risk assessment is not expected to be necessary.

In biocidal product Sikkens Cetol HLS Plus[BP] is 2-butanone oxime (CAS no 96-92-7) present at a concentration less than 1%. The co-formulant 2-butanone oxime will be replaced with a substance very similary, and in the same concentration. Both substances are anti-skinning agents, and are expected to have the same properties.

Physical/chemical properties:
It is assessed that the change of recipe for Product family Sikkens cetol HLS plus[BP] will not adversely affect the physic-chemical properties.

Efficacy:
The replacement of the anti-skinning agent is a minor change that does not require new biological testing.

Impact of change on human health
The change has no effect on this point

Impact of change on environmental risk assessment
The change has no effect on this point

Classification and labelling

Concerning the classification and labelling the intended minor change will eliminate 2-butanone oxime from the formulations. As a result, the notification that the biocidal product "contains butan-2-oxime" will disappear from the labelling of the product.

An overview of the labelling of both substances

Labelling of substance 2-butanone oxime (CAS 96-29-7)

Current CLP

Danger!
Acute Tox 4: H312 - Harmful in contact with skin
Eye Dam 1: H318 - Causes serious eye damage
Skin Sens 1: H317 - May cause an allergic skin reaction
Carc. 2 : H351 - Suspected of causing cancer

Drafted by 15th ATP

Danger!
Carc. 1B: H350 - May cause cancer
Acute Tox. 4: H312 - Harmful in contact with skin
Acute Tox. 3: H301 - Toxic if swallowed
STOT SE 3: H336 - May cause drowsiness or dizziness
STOT SE 1: H370 - Causes damage to organs (upper respiratory)
STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure (blood system)
Skin Irr. 2: H315 - Causes skin irritation
Eye Dam. 1: H318 - Causes serious eye damage
Skin Sens. 1: H317 - May cause an allergic skin reaction

Labelling of new substance

Current CLP

Warning!

Acute tox 4: H302 - Harmful if swallowed
Eye Irr 2: H319 - Causes serious eye irritation
STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure
Aq Chron 3: H412 - Harmful to aquatic life with long-lasting effects

Labelling aspect

Labelling aspect	**Actual formulation** (With 2-butanone oxime)	**New formulation**
The GHS signal word as used on the labels for EU	No Signal word	No Signal word
The hazardous ingredients for labels for EU	None	None

The hazard statement codes on the label for EU	H412	H412
All the GHS precautionary statement codes used for EU	P102, P101, P262, P312, P501	P102, P101, P262, P312, P501
The EU additional warning phrase for on the label	Not applicable	Not applicable
Other aspects	Contain IPBC and 2-butonaon oxime. May produce an allergic reaction. Repeated exposure may caus ski dryness or cracking	Contains IPBC. May produce an allergic reaction. Repeated exposure may cause skin dryness or cracking

The formulations do not differ in CLP requirements / elements. The new formulation does not contain 2-butanone oxime. Therefore the label element “and 2-butanone oxime” will be removed from the label as a consequence of its absence.

4.3 Overall conclusion

Based on the argumentation above, the described changes (minor change) can be accepted.