Product Assessment Report

MIRECIDE-TC/94

June 2012

Updated document (April 2016)
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Updated document (March 2021)

Internal registration/file no:	
Authorisation/Registration no:	ES/AA-2012-08-00043
Granting date/entry into force of authorisation/ registration:	19/10/2012
Expiry date of authorisation/ registration:	30/10/2025
Active ingredient:	IPBC and Propiconazole
Product type:	8

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

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Laboratorios Miret S.A. (LAMIRSA)
Address:	Pol. Ind. Can Parellada C/ Géminis, 4
City:	Terrassa (Barcelona)
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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mr. Roger Segret
Function:	Regulatory Affairs Manager
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1.2 Current authorisation holder[1]

Company Name:	Laboratorios Miret S.A. (LAMIRSA)
Address:	Pol. Ind. Can Parellada C/ Géminis 4
City:	Terrassa (Barcelona)
Postal Code:	08228
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Telephone:	+34 93 731 12 61
Fax:	+34 93 731 42 80
E-mail address:	rsegret@lamirsa.com
Letter of appointment for the applicant to represent the	No applicable

[1] Applies only to existing authorisations

authorisation holder provided (yes/no):	

1.3 Proposed authorisation holder

Company Name:	Laboratorios Miret S.A. (LAMIRSA)
Address:	Pol. Ind. Can Parellada C/ Géminis 4
City:	Terrassa (Barcelona)
Postal Code:	08228
Country:	Spain
Telephone:	+34 93 731 12 61
Fax:	+34 93 731 42 80
E-mail address:	rsegret@lamirsa.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No applicable

1.4 Information about the product application

Application received:	29 June 2010
Application reported complete:	-
Type of application:	authorisation
Further information:	ES has MIRECIDE-TC/94 currently authorised under national legislation for use as a wood preservative (PT8). The current application is for PT8 use and that will be assessed and authorised under 98/8/EC.

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	MIRECIDE-TC/94
Manufacturer's development code number(s), if appropriate:	
Product type:	8
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	IPBC (3-Iodo-2-propynyl butyl carbamate): 10.3% Propiconazole (1H-1,2,4-Triazole, 1-[[2-(2,4-dichloro phenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-): 6.4%
Formulation type:	Emulsion
Ready to use product (yes/no):	No (the biocidal product is diluted in water)
Is the product the very same (identity	No

and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Automated industrial dipping of fresh wood in a bath of water
Target organisms:	Blue stain fungi and mould
Category of users:	Industrial user
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:	2 cycles of immersion per day, each of 60 minutes, with an application rate of 2-3%
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	please, see the authorisation
Use Restrictions:	Only 2 cycles of immersion of 60 minutes per day

1.5.3 Information on active substance(s)[2]

Active substance chemical name:	IPBC	Propiconazole
CAS No:	55406-53-6	60207-90-1
EC No:	259-627-5	262-104-4
Purity (minimum, g/kg or g/l):	980 g/kg	930 g/kg
Inclusion directive:	Directive 2008/79/EC	Directive 2008/78/EC
Date of inclusion:	1 July 2010	1 April 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes	yes
Manufacturer of active substance(s) used in the biocidal product:	European Union IPBC Task Force	Syngenta European Center
Company Name:	ISP Switzerland GmbH	Syngenta Crop Protection AG
Address:	LIndestrasse10	Schwarzwaldallee, 215

[2] Please insert additional columns as necessary

City:	Baar	Basle
Postal Code:	CH-6340	CH - 4002
Country:	Switzerland	Switzerland
Telephone:	+34-91-375 30 26	+41 61 323 9242
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E-mail address:		james.pemberton@syngenta.com
Manufacturer of active substance(s) used in the biocidal product:	LANXESS Deutschland GmbH	LANXESS Deutschland GmbH
Company Name:	LANXESS Deutschland GmbH	LANXESS Deutschland GmbH
Address:	Building Q18	Building Q18
City:	Leverkusen	Leverkusen
Postal Code:	51369	51369
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1.5.4 Information on the substance(s) of concern[3]

The biocidal product does not contain any substances of concern according to the Technical Notes for Guidance on data requirements.

ADDENDUM (MARCH 2021)

NA-MIC (BC-ST050725-08) was submitted by the applicant regarding a change of composition in the co-formulants. Please, see confidential PAR in order to check the changes. SoCs were not identified.

1.6 Documentation

1.6.1 Data submitted in relation to product application

New data were submitted in relation to analytical methods in human body fluid and tissues for IPBC when this active substance has been evaluated under PT6 by the RMS, DK (please, see section 2.3.2).

The classification of the biocidal product has been updated in February 2017 because a new classification of the active substance IPBC was included in 6th ATP of CLP Regulation.

ADDENDUM (MARCH 2021):

The classification of the biocidal product has to be modified because of the new classification of propiconazole in the 13 ATP of Annex VI of CLP Regulation.

[3] Please insert additional columns as necessary

1.6.2 Access to documentation

The applicant has submitted a letter of access of IPBC from ISP (Switzerland) AG as member of the European Union IPBC Task Force and a letter of access of propiconazole from Syngenta Crop Protection AG.

All substances data sheets are included in the dossier.

2 Summary of the product assessment

2.1 Identity related issues

The active substances were included in the Annex I of Directive 98/8/EC (Directive 2008/79/EC of 28 July 2008 to include IPBC and Directive 2008/78/EC of 25 July 2008 to include propiconazole as active substances in Annex I). The letters of access are from ISP (Switzerland) AG as member of the European Union IPBC Task Force and from Syngenta Crop Protection AG, respectively.

The co-formulants are not substances of concern according to the Technical Notes for Guidance on data requirements. The formulation includes several emulsifiers and solvents. Information on the full composition of the product and assessment are detailed in confidential PAR.

2.2 Classification, labelling and packaging

The information about the classification and labelling according to Directive 1999/45/EC has been removed taking into account that the biocidal product should be classified and labelled according to CLP regulation.

2.2.1 Harmonised classification and labelling of the biocidal product

According to Regulation 1272/2008 (Until 1 June 2015, mixtures shall be classified, labelled and packaged in accordance with Directive 1999/45/EC.):

ADDENDUM (MARCH 2021):

The classification of the biocidal product has to be modified because of the new classification of propiconazole in the 13 ATP of Annex VI of CLP Regulation.

GHS Pictograms		
Signal Word	Danger	
Classification	Hazard class and category: Hazard statement	Category 2; Skin Irrit. 2 Eye Damage Cat.1 Skin Sens Cat.1 STOT-RE 1 Repr. 1B Acute 1 Chronic 2 H315: Causes skin irritation H317: May cause an allergic skin reaction H318: Causes serious eye damage

		H372: Causes damage to organs through prolonged or repeated exposure (larynx). H360D May damage the unborn child H410: Very toxic to aquatic life with long lasting effects
General precautionary statement	P102: Keep out of reach of children	
Prevention precautionary statement	P262: Do not get in eyes, on skin, or on clothing P280: Wear protective gloves/protective clothing/eye protection/face protection	
Response precautionary statements		
Storage precautionary statements	P403+P233: Store in a well-ventilated place. Keep container tightly closed	
Disposal precautionary statements	P501: Dispose of contents/containers to hazardous waste facilities in accordance with national regulations.	

2.2.2 Packaging of the biocidal product

Drums of 25, 60 and 230 L containing 25, 55 and 200 kg respectively and a container of 1000 L containing 950 kg. All of them are high density polyethylene (HDPE) container.

2.3 Physico/chemical properties and analytical methods

IPBC is stable at room temperature and at 40ºC for 8 weeks. IPBC is not highly flammable. It has no pyrophoric property and it does not undergo spontaneous combustion. IPBC is not explosive.

The recommended container material for IPBC is protected steel drums.

Residues in air were not necessary because IPBC is not volatile and spray applications only involve non-respirable particles.

An analytical method for the determination of residues of IPBC in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs.

Regarding Propiconazole, due to the small spectral overlap, only a slow direct photochemical degradation can be expected. The water solubility is moderate and is independent of the pH.
Propiconazole is hydrolytically stable in the pH-range between 1 and 13. The log Kow is 3.72 at neutral pH. Propiconazole is completely miscible in many organic solvents, and solubility in n-hexane is 47 g/l. Flammability, explosive and oxidising properties are not critical.

The methods of analysis of active substance as manufactured and for determination of impurities which are present at quantities > 0.1 g/kg in the active substance as manufactured have been validated and shown to be sufficiently specific, linear, accurate and precise. The methods for residue analysis in different matrices (soil, surface water, sediment, potable water and air), as appropriate for the assessed uses, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

2.3.1 Physico-chemical properties

Regarding the active substances, the table has not been filled in because a letter of access has been submitted for them. Regarding the biocidal product, these are the physico-chemical properties:

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

	Method	Purity/ Specification	Results	Reference
Physical state and nature	Visual inspection	IPBC:9.5-10.5% Propiconazole:6.0-6.5%	Concentrated emulsifying liquid	B.3.1.01
Colour	Visual inspection		Yellow.	B.3.1.01
Odour	Olfactory inspection		Characteristic odour	B.3.1.01
Explosive properties			The biocidal product does not present explosive properties.	B.3.2
Oxidizing properties			The biocidal product does not present oxidising properties.	B.3.3
Flash point	EC method A.9 (closed cup)		79 ± 1 °C	B.3.4.01
Autoflammability	EC method A.15		Self-ignition temperature: 285 °C	B.3.4.04
Other indications of flammability	EC method A.12		The biocidal product is not considered to be hazardous as no spontaneous ignition occurred and no evolution of flammable gas at a rate > 1 L/kg of the test item per hour was observed.	B.3.4.02
Acidity / Alkalinity	CIPAC Method MT 75.3		pH = 5.9 The determination of the acidity or alkalinity, respectively, is not applicable because the pH-value of the formulation is between 4 and 10.	B.3.5.01
Relative density / bulk density	EC method A.3		Relative density: D_4^{20} = 0.982 The determination of the bulk density is not applicable because the biocidal product is liquid.	B.3.6.01
Accelerated storage stability – stability and shelf life	CIPAC MT 46.3		The formulation is stable at 40 °C for 8 weeks. No significant changes of physicochemical properties were observed. IPBC content before storage: 10.2% IPBC content after storage: 9.9% Propiconazole content before storage: 6.2% Propiconazole content after storage: 6.1%	B.3.7.01
Low temperature stability	CIPAC MT 39.3		The formulation is stable at 0 °C for 7 days. No significant changes of appearance were observed. After the storage period the volume of the separated material at the bottom of the tube was determined to be < 0.01 mL.	B.3.7.02
Storage stability – Long Term	Technical Monograph No. 17, Guidelines for the Specifying the Shelf Life of Plant Protection Products, May 1993		No physical changes were observed. The loss of weight after 2 years storage was ≤ 0.2 %.. The physical-chemical parameters were within the inter-national specifications. After 24 months storage at 20 °C the average content of IPBC was 9.8% corresponding to 99 % of the initial content. The average content of propiconazole was 6.0% corresponding to 99 % of the initial content	B.3.7.03
Technical characteristics in	CIPAC MT 47.1 (persistent		Observed foam volume after	B.3.8.01

	Method	Purity/ Specification	Results	Reference
dependence of the formulation type	foaming)		10 sec:6.6 mL 1 min:6.3 mL 3 min:6.0 mL 12 min:5.3 mL	
Compatibility with other products			Not applicable since the biocidal product will not be used with other products including other biocidal products.	
Surface tension	EC method A.5		32.3 mN/m at 20 °C Surface tension was determined using an aqueous solution of the test item (1 g/L).	B.3.10.01
Viscosity	OECD guideline 114 / CIPAC MT 192		The viscosity of the biocidal product at 20 °C ± 0.2 °C ranged between 23 and 31 mPa s at a shear rate from 20 to 100 1/s. The viscosity of the biocidal product was determined to be 18.7 mPa s at 20 °C ± 0.2 °C, and 9.57 mPa s at 40 °C ± 0.2 °C at a constant shear rate of 1000 1/s.	B.3.10.01
Particle size distribution			Not applicable because the biocidal product is liquid.	
Persistent Foaming	CIPAC,MT 47.1and MT18		The concentration of use was 2% test item in water. After 10 sec a foam volume of 6.6mL was observed. After 1 min a foam volume of 6.3 mL; after 12 min a foam volume of 5.3 mL	B.3.8.01
Emulsifiability/ Emulsion stability/ Re-emulsifiability	CIPAC MT 36.3		Emulsionable product. The emulsion is stable for more than half an hour.After 2h some phase separation is observed, except for the higher concentration, where in general the sample is homogeneus. After 24h all the samples are separated in phases from lower than 1mm (lower concentrations) to 2-3mm (higher concentration). Anyhow the sample is readily re-emulsified after shaking the sample and after the re-emulsification process the samples are satble for the first half an hour as stated in the standard	B.3.8.05
Pyrophoric Properties	Directive 92/69/EEC, Annex V,A.13 EEC		The test item MIRECIDE_TC/94 did not ignite within five minutes when added to an inert carrier. Therefore, the test item is considered to be not pyrophoric	B.3.4.03

2.3.2 Analytical methods

IPBC

	Principle of method
Technical active substance as manufactured:	HPLC-UV and GC-FID.
Impurities in technical active substance:	HPLC-UV and GC-FID
active substance in the formulation:	HPLC- DAD and UV detector

PROPICONAZOLE

	Principle of method
Technical active substance as manufactured:	GC-FID
Impurities in technical active substance:	GC-FID
active substance in the formulation:	HPLC- DAD and UV detector

Relevant residues for monitoring human body fluid and tissues were PBC and IPBC. In blood and muscle IPBC degraded rapidly (to PBC) and it was not possible to determine IPBC residues above 70%.
Analysis was done by HPLC using reversed-phase liquid chromatography and a water / methanol gradient on a C18-column.
Detection was made with a MS/MS system using positive electrospray ionisation.
LOQ for PBC and IPBC in urine and blood at 0.05 mg/L.
LOQ for PBC and IPBC in meat at 0.1 mg/L.

2.4 Risk assessment for Physico-chemical properties

The biocidal product does not present explosive or oxidising properties. Its flash point is 79 °C and its self-ignition temperature 285 °C. The formulation does not deliver indications of pyrophoric properties and does not evolve flammable gases when it comes in contact with water.

The biocidal product was found to be stable at 40 °C for 8 weeks and stable at low temperatures (0 °C for 7 days). No significant changes of physicochemical properties were observed.

Moreover, the product showed no modification through 24 months storage period. The packaging material container and lid showed no cracking, fogging discoloration or distortion or change in weight. There is no seepage through the container walls or lid. The physical-chemical parameters were within the inter-national specifications. After 24 months storage at 20 °C the average content of IPBC was 9.8% corresponding to 99 % of the initial content. The average content of propiconazole was 6.0% corresponding to 99 % of the initial content.

The product can be defined as emulsionable. This emulsion is stable for more than half an hour.

On the basis of these physical-chemical properties and the storage stability tests, the biocidal product is considered to be of low hazard and as a result no potential risk to users is given.

2.5 Effectiveness against target organisms

We do not have new data/information submitted for the active substance about efficacy.

The biocide MIRECIDE-TC/94 contains the fungicide components Propiconazole and IPBC and it avoids the microbiologic development in the wood during the storage. It is highly active against all sorts of fungi in the plant protection sector avoiding the fungi growth, whose proliferation is favoured by several factors as, for example, pH value, humidity and working temperature.

MIRECIDE-TC/94 is a concentrated emulsion which makes use of water to introduce the active ingredients into the wood.
Propiconazole effectively acts against sap stain and moulds, blue stain, decay and dry rot fungi, as well as against basidiomycetes. IPBC is effective against decay and dry rot. By penetrating into the timber wood it protects also against moisture and weather influences.

Propiconazole has been examined for efficacy in a wide range of applications for wood preservation (product type 8 of the EU Biocidal Product Directive), i.e. superficial treatment of wood (spraying, dipping and brushing against sap stain and moulds, blue stain), penetrative treatment of wood (vacuum pressure and double vacuum against blue stain and decay), mortar adjacent to wood (against dry rot).
IPBC containing biocidal products (wood preservatives) have been demonstrated sufficient effective against wood discolouring and wood-rotting fungi.

The biocidal product MIRECIDE-TC/94 is highly effective against a wide variety of fungal species, e.g. blue stain fungi (*Aureobasidium pullulans, Sclerophoma pityophila*), sapstainers and wood rotting fungi and against moulds (*Aspergillus niger, Penicillium citrinum, Alternaria alternata*).

The biocidal product has been tested according to CEN/TS-18082:2005 (Methodology of Forest Industry Service of the Centre of Forest research-CIFOR of the National Institute of Agrarian

Research (INIA) under the Ministry of Science and Technology *"Wood preservatives. Determinations of the fungicidal effectiveness of preservative products for green wood in sawmill. Field test"*). The results provided confirm the broad efficacy against relevant fungal strains commonly found on wood (specie tested was *Pinus radiata*). The results showed an initial retention of 180g/m^2 when the dimension of test specimen was 20mm X 100 x 420mm. No pre-treatment of panels was performed and the ageing of sample was 3 days after cutting. MIRECIDE-TC/94 showed efficacy against blue stain fungi and mould from a concentration of 2% when fresh wood was treated for 10 seconds by immersion procedure.

2.5.1 Dose / mode of action / known limitations / resistance

The usual dose of MIRECIDE-TC/94 for all processes ranges from 2–3 % (w/w) in a bath of water into which timber is dipped. The biocidal product is automatically loaded into the treatment vessels via metered pumping systems.

As a mixture of two ingredients, advantage is taken of the combined action of an ergosterol biosynthesis inhibiting azole (propiconazole) and a carbamate (IPBC).

The mode of action of propiconazole, as other triazole, is to inhibit the C14 demethylation step in the ergosterol biosynthesis of fungi. All four isomers of propiconazole provide biological activity. The intrinsic activity of each isomer is different from pathogen to pathogen. The broad spectrum and high level of activity of propiconazole is the result of the combined activity of the single isomers.

The principal mode of action of IPBC is thought through the iodine toxicity.

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)

MIRECIDE-TC/94 is a water-dispersable wood preservative concentrate for industrial use.

The concentrated product contains 10.3% (w/w) IPBC and 6.4% (w/w) propiconazole. Timber treatment is conducted by dipping.

The usual dose of MIRECIDE-TC/94 for all processes ranges from 2–3 % (w/w) in a bath of water into which timber is dipped. The higher dose will be considered in the exposure calculations, as a worst case. The biocidal product is automatically loaded into the treatment vessels via metered pumping systems.

2.6.2 Assessment of exposure to humans and the environment

Regarding human exposure no studies have been submitted; therefore, the exposure assessment has been performed using the HEEG opinion, 2009, "Defaults and appropriate models to assess human exposure for dipping processes (PT 8)" and the Technical Notes for Guidance on Human Exposure.

The environmental exposure assessment is based on the OECD series on emission scenario documents (OECD ESD) "Emission Scenario Document for Wood Preservatives (Parts 1 and 2)" (OECD, 2003). Where necessary the "Technical Guidance Document (TGD) for Risk Assessment" (European Commission, 2003) is also taken into consideration. Three main scenarios have been addressed: industrial application, industrial storage, and in-service leaching from treated wood.

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

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product does not contain any substances of concern according to the Technical Notes for Guidance on data requirements.

ADDENDUM (MARCH 2021)

NA-MIC (BC-ST050725-08) was submitted by the applicant regarding a change of composition in the co-formulants. Please, see confidential PAR in order to check the changes. The changes in the composition do not affect the toxicological classification and substances of concerns were not identified.

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.

Dermal absorption

Dermal absorption studies with MIRECIDE-TC/94 have not been conducted. For products containing 17, 2.4 and 0.6% IPBC dermal absorption values of 1.6, 10, and 30%, respectively, have been set in the CAR by RMS Denmark. For dilute solutions containing < 0.5% - 0.6% IPBC, the default dermal absorption value of 100% has been set. Therefore, a dermal absorption value of 10% will be used for the concentrated biocidal product (10.3% IPBC) and 100% will be assumed for the in-use dilution of the biocidal product (0.1-0.3% IPBC).

For products containing 10% propiconazole, a dermal absorption value of 1% has been set in the CAR by RMS Finland. For dilute solutions (*ca* 0.1% propiconazole), a dermal absorption value of 2% has been set. Therefore, a dermal absorption value of 2% will be used for the concentrated biocidal product (6.4% propiconazole) and 2% will be assumed for the in-use dilution of the biocidal product (0.06-0.2% propiconazole).

Acute toxicity

Acute toxicity tests show that the biocidal product is non-toxic to rats by the oral route (oral LD_{50} > 2000 mg/kg) and dermal route (dermal LD_{50} > 2000 mg/kg). Inhalation toxicity is not required because the product is not volatile nor applied in a manner that generates respirable aerosols.

Irritation and corrosivity

The skin irritation potential of MIRECIDE-TC/94 was investigated in rabbits conducted according to OECD-guideline 404. A single dermal application of the test item MIRECIDE-TC/94 to two

rabbits at a dose of 0.5 mL showed irritant effects which were irreversible within 14 days. The test material is irritating to rabbit skin. The observed effects do lead to a classification as a skin irritant.

Species	Method	Average score 24, 48, 72 h		Reversibility	Result	Reference
		Erythema	Oedema			
Rabbit	OECD 404	2.17	2.67	Not reversible	Irritating	B6.2.1_01

The eye irritation potential of MIRECIDE-TC/94 was investigated in one female New Zealand White rabbit. The study was conducted according to OECD Guideline 405. Single ocular instillation of the test item MIRECIDE-TC/94 to a single rabbit at a dose of 0.1 mL produced strong irritant effects, which were not reversible within 21 days. Therefore, MIRECIDE-TC/94 has to be classified as a severe eye irritant.

Species	Method	Average score 24, 48, 72 h				Reversibility	Result	Reference
		Cornea	Iris	Conjunctiva				
				Redness	Chemosis			
Rabbit	OECD 405	#	#	3.00	4.00	Not reversible	Severely irritating	B6.2.2_01

[#] Eyelids were almost closed due to swelling, and therefore iris and cornea could not be seen

Skin sensitisation

Sensitisation studies with MIRECIDE-TC/94 have not been conducted. The product contains 6.4% propiconazole and 10.3% IPBC and both active substances are classified as sensitizers. The toxicological properties of the biocidal product can therefore be assessed using the conventional method described in Directive 1999/45/EC (DPD) and the guidance for classifying mixtures under CLP. According to DPD and to CLP, the preparation has to be classified as a skin sensitizer if an ingredient classified as skin sensitizer is present at ≥ 1%. This is the case and the biocidal product is skin sensitizer.

Therefore, the formulation is irritating to skin, holds risk of serious damage to eyes and may cause sensitisation by skin contact. With regard to its toxicological properties, the biocidal product has to be classified as irritant. It has to be labelled with the hazard symbols Xi and the R-phrases R38-41-43 according to Directive 1999/45/EC and H315, H317, H318 and H372 (larynx) according to CLP Regulation.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”.

Other effects of IPBC:

This active substance was classified in 6th ATP of CLP Regulation.

616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	Acute Tox. 3 Acute Tox. 4 STOT RE 1 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H372 (larynx) H318 H317 H400 H410	GHS06 GHS08 GHS05 GHS09 Dgr	H302 H331 H318 H317 H372 (larynx) H410	M=10 M=1

According to the information of the biocidal product, acute oral toxicity was defined as oral LD50 > 2000 mg/kg and, on based of different studies, the following classification was identified:

H315: Causes skin irritation

H317: May cause an allergic skin reaction
H318: Causes serious eye damage

In relation to inhalation acute toxicity, no study with the product was submitted but the justification was considered acceptable because the product is not volatile nor applied in a manner that generates respirable aerosols.

Regarding the hazard statement H372 (larynx), and taking into account the concentration of IPBC in the formulation (> 10%) and CLP criteria, the biocidal product will be classified with H372: Causes damage to organs through prolonged or repeated exposure (larynx).

ADDENDUM (MARCH 2021)

NA-MIC (BC-ST050725-08) was submitted by the applicant regarding a change of composition in the co-formulants. The content of active substances is not changed. Please, see confidential PAR in order to check the changes. No new studies were submitted. The changes in the composition do not affect the toxicological classification. However, the classification of the biocidal product has to be modified because of the new classification of propiconazole in the 13 ATP of Annex VI of CLP Regulation.

Classification		**Labelling**		
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms, Signal Word Code(s)**
Acute Tox. 4	H302	H302		GHS09 GHS08 GHS07 Dgr
Skin Sens. 1	H317	H317		
Aquatic Acute 1	H400			
Aquatic Chronic 1	H410	H410		
Repr. 1B	H360D	H360D		

According to this, H360D (May damage the unborn child) is added to the classification and labelling of the biocidal product taking into account the concentration of propiconazole in MIRECIDE TC/94 and the generic concentration limits triggering classification of a mixture in CLP regulation.

In addition, the Assessment of the ED properties of active substances and non-active substances has been carried out. Please, the information is in the Confidential PAR but none of the co-formulants contained in the biocidal product were identified as endocrine disruptors after assessment.

2.7.2 Exposure

2.7.2.1 Exposure of industrial users

Primary Exposure

The biocidal product (diluted to 2-3%) is applied by dipping. Primary exposure occurs during the handling of freshly treated wood and during cleaning of the dipping tank.

The activities of the industrial users are:

Mixing/loading:

Mixing/loading is a fully automated process in a closed system. Mixing occurs in large tanks to which the product is automatically supplied in the required quantity via hoses. There is no manual interaction needed. Loading of the dipping tank from the mixing system also occurs in an automated, closed system, without any need for manual interaction by the operator. The concentration of active substance may be checked from time to time and adjusted by additional supply of product, all within the same automated, closed system.

The **process of mixing/loading** for dipping of wood in industrial premises is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No exposure calculation is provided for this activity.

Application:

The application process itself occurs in a large tank, which is opened during loading with wood but closed during treatment. Loading and unloading with wood occurs mechanically by forklift trucks. For the actual treatment process, timber stacks are loaded onto a forklift integrated in the dipping / deluging system or in the spray tunnel. Before removing treated wood from the system, excessive treatment solution is allowed to drain off. Afterwards it is transported mechanically to the storage place. There is no manual interaction needed during the entire process.

The **application process** in industrial premises is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No separate exposure calculation is provided for this activity. However, the model applied for post-application handling as described below may partly also cover potential exposure during the treatment process itself. This model may be best described as "intermittent contact with wet objects".

Post-application

Post-application exposure to the product may occur during manual contact during handling of treated wood. Timber to be treated is generally stacked to large batches which are transported mechanically by forklift trucks. After treatment, they remain on the fork lift above the tank for a certain while (initial drying), before they are transferred to a storage place by a fork lift truck for final drying and fixation of the impregnation. Usually, there should be no manual contact with treated wood until the product has completely dried.

Maintenance/Cleaning:

Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. However, such activities are of short duration (few minutes to few hours) and occur only occasionally (once to a few times a year or even less). Potential contamination is expected to be limited to hands.

Another potential source for contamination with residual product is cleaning the inner surface of the dipping tank. This task is done once a year at maximum. The cleaning process lasts for a few hours. Whenever cleaning is done, the potential for contamination is high, both by dermal contact and by inhalation. Therefore an extensive personal protection is needed.

Cleaning is considered to represent the worst case among the possible maintenance activities with regard to the potential level of exposure. Therefore, as cleaning is not well described by the available models, the Handling Model 1 is chosen to assess the exposure risk during cleaning.

2.7.2.1.1 Automated dipping of woden articles

At TM III 2009 it was agreed from a HEEG opinion that for automated dipping processes using a fork-lift it is appropriate to use Handling Model 1 (TNsG Human Exposure to Biocidal Products 2002, Part 2 p162, and the User Guidance, 2004, p 26 & p 41) to predict exposure. This conclusion was based on the findings of a German exposure study, which observed qualitatively that the dermal exposure pattern of automated dipping is comparable to that of the vacuum-pressure process, i.e. exposure occurs through the intermittent handling of wet-preserved timber. Exposure will primarily be via the dermal route. This is a long-term exposure scenario.

The following assumptions have been considered in the calculations:

Hands	**1080 mg/cycle** (actual, 75th percentile)
Glove penetration	**not considered for actual hand exposure values**
Body	**8570 mg/cycle** (potential, 75th percentile)
Clothing penetration	**10%** (impermeable coverall)
Inhalation	**1.9 mg/m³** (potential, 50th percentile)
Inhalation rate	**1.25 m³/h** (default)
Duration	**4 cycle (HEEG Opinion 2009**)
Body weight	**60 kg** (default)

The HEEG Opinion of TM III 2009 (Manual of Technical Agreements 4.2.9.8) assumes 4 dipping cycles of 60 minutes per cycle are performed per day by automated dipping. However, ES CA has estimated the exposure for 4 cycles and a risk is derived. Therefore, ES CA has looked for a safe scenario and it will consist on 2 cycles only. The results are shown in Table 2.7.2.1.1-1:

Table -1.7.2.1.1-1: Exposure assessment for industrial workers cleaning a dipping tank

Handling Model 1	**Propiconazole**	**IPBC**	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %	0.20 %	0.30 %
Potential body exposure				
Indicative value mg/cycle	8570	8570	8570	8570
No. of cycles per day	**2**	**2**	**4**	**4**
Potential dermal deposit mg	17140	17140	34280	34280
Clothing type	Cotton coveralls	Cotton coveralls	Cotton coveralls	Cotton coveralls
Clothing penetration %	10%	10%	10%	10%
Actual dermal deposit (product) mg	1714	1714	3428	3428
Hand exposure				
Indicative value mg/cycle (actual)	1080	1080	1080	1080
No. of cycles per day	**2**	**2**	**4**	**4**
Hand deposit mg	2160	2160	4320	4320
Mitigation by gloves	Not applicable	Not applicable	Not applicable	Not applicable
Actual dermal deposit (product) mg	2160	2160	4320	4320
Total dermal exposure				
Total dermal deposit (product) mg	3874	3874	7748	7748
Active substance mg	7.748	11.622	15.496	23.244
Dermal absorption %	2	100	2	100
Systemic exposure via dermal route mg	0.155	11.622	0.310	23.244
Exposure by inhalation				
Indicative value mg/min	1.9	1.9	1.9	1.9
Duration min	180	180	180	180
Inhalation rate m^3/h	1.25	1.25	1.25	1.25
Mitigation by RPE (PF)	1	1	1	1
Inhaled (product) mg	7.125	7.125	7.125	7.125
Systemic exposure mg kg^{-1} day^{-1}	0.01425	0.021375	0.01425	0.021375

Systemic Exposure				
Total systemic exposure a.s. mg	0.169	11.643	0.324	23.265
Body weight kg	60	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	0.0028201	0.1940562	0.005402833	0.38775625

2.7.2.1.2 Cleaning out Dipping Tank after Use

Cleaning of the inner surface of the dipping tank would be undertaken infrequently, possibly once a year. The routes of exposure for operators cleaning out tanks would be via the skin and inhalation. Cleaning of internal surfaces of dipping tanks is not included in the current TNsG models.
To attempt to model this primary exposure scenario, the indicative exposure from the model for the industrial intermittent handling of solvent-damp wood and associated equipment was used. The model data are derived from data relating to industrial timber treatment using double-vacuum pressure, with a cycle duration of 180 minutes (User Guidance, p.41). Hand exposure is actual exposure inside gloves. The potential for contamination of operators is high and consequently, extensive personal protection is required.

Cleaning out dipping tank, has been assessed with Handling Model 1: Intermittent handling of water-wet or solvent-damp wood and associated equipment (TNsG 2002, Part 2, p.162 as revised by the User Guidance, p.26; 75th percentile for dermal exposure and 50th percentile for inhalation). The following assumptions have been considered in the calculations:

Hands	**1080 mg/cycle** (actual, 75th percentile)
Glove penetration	**not considered for actual hand exposure values**
Body	**8570 mg/cycle** (potential, 75th percentile)
Clothing penetration	**10%** (impermeable coverall)
Inhalation	**1.9 mg/m³** (potential, 50th percentile)
Inhalation rate	**1.25 m³/h** (default)
Duration	**1 cycle (180 min** (TNsG, Excel database))
Body weight	**60 kg** (default)

The data resulted in **systemic doses 0.0012 and 0.0715 mg/kg bw/day** for propiconazole and IPBC, respectively (see Table 2.7.2.1.2-1):

Table 2.7.2.1.2-1: Exposure assessment for industrial workers cleaning a dipping tank

Handling Model 1	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %
Potential body exposure		
Indicative value mg/cycle	8570	8570
No. of cycles per day	1	1
Potential dermal deposit mg	8570	8570
Clothing type	Cotton coveralls	Cotton coveralls
Clothing penetration %	10%	10%
Actual dermal deposit (product) mg	857	857
Hand exposure		

Indicative value mg/cycle (actual) No. of cycles per day Hand deposit mg Mitigation by gloves Actual dermal deposit (product) mg	1080 1 1080 Not applicable 1080	1080 1 1080 Not applicable 1080
Total dermal exposure		
Total dermal deposit (product) mg Active substance mg Dermal absorption % Systemic exposure via dermal route mg	1937 3.874 2 0.077	1937 5.811 100 5.811
Exposure by inhalation		
Indicative value mg/min Duration min Inhalation rate m^3/h Mitigation by RPE (PF) Inhaled (product) mg Systemic exposure mg kg^{-1} day^{-1}	1.9 180 1.25 1 7.125 0.01425	1.9 180 1.25 1 7.125 0.021375
Systemic Exposure		
Total systemic exposure a.s. mg Body weight kg Systemic exposure mg kg^{-1} day^{-1}	0.092 60 1.53×10^{-3}	5.832 60 9.72×10^{-2}

2.7.2.1.3 Summary of primary exposure

The overall summary of primary systemic exposure is given in Table 2.7.2.1.3-1:

Table 2.7.2.1.3-1: Summary of primary exposure

Scenario		**Systemic dose [mg/kg bw/day]**	
		Propiconazole	**IPBC**
Dipping, incl. handling	2 cycles	Inhalation: 2.37×10^{-4} Dermal: 2.58×10^{-3} **Total: 2.82×10^{-3}**	Inhalation: 3.5625×10^{-4} Dermal: 0.19 **Total: 0.19**
	4cycles	Inhalation: 2.375×10^{-4} Dermal: 5.16×10^{-3} **Total: 5.40×10^{-3}**	Inhalation: 3.56×10^{-4} Dermal: 0.39 **Total: 0.39**
Cleaning out dipping tank after use		Inhalation: 2.37×10^{-4} Dermal: 1.29×10^{-3} **Total: 1.53×10^{-3}**	Inhalation: 3.56×10^{-4} Dermal: 9.68×10^{-2} **Total: 9.72×10^{-2}**

2.7.2.2 Exposure of professional users

Not intended.

2.7.2.3 Exposure of non-professional users and the general public

Not intended.

2.7.2.4 Indirect exposure of the general public: Secondary Exposure

2.7.2.4.1 Acute phase: Adult – sanding treated wood posts

Inhalation route

A person (non professional) is sanding the surface of treated wood posts (4 cm x 4 cm x 2.5 m, surface area of 4032 cm^2) for an outdoor play area. The active substances are in the outer 1 cm layer. A nominal application rate of IPBC and propiconazole of 0.36 and 0.23 g/m², respectively, can be estimated from the available leaching test.

The propiconazole and IPBC concentration in the in outer 1-cm layer would be 0.031 and 0.048 mg/cm³, respectively. The density of the wood is assumed 0.4 g/cm³.

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 2.7.2.4.1-1. **Systemic exposure estimates** for propiconazole and IPBC are **8.03×10^{-6}** and **1.26×10^{-5} mg/kg bw/day**, respectively.

Table 2.7.2.4.1-1: Exposure during sanding of treated wood

Sanding of treated wood	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %
Concentration in wood		
Application rate (a.s.) g/m^2	0.23	0.36
Application rate (a.s.) mg/cm^2	0.023	0.036
Area of wood to be sanded m^2	0.4032	0.4032
Volume of outer layer cm^3 (Layer thickness 1 cm)	3008	3008
Amount in sanded wood (a.s.) mg	92.74	145.15
Concentration in wood (a.s) mg/cm^3	0.031	0.048
Exposure by inhalation		
Wood dust concentration in air mg/m^3	5	5
Density of wood g/cm^3	0.4	0.4
Exposure duration min	60	60
Inhalation rate m^3/h	1.25	1.25
Mitigation by RPE (PF)	1	1
Inhaled (a.s.) mg	4.82×10^{-4}	7.54×10^{-4}
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	8.03×10^{-6}	1.26×10^{-5}

Dermal route (hands – no gloves worn)

The highest concentration on the surface is 0.023 mg propiconazole and 0.036 mg IPBC per cm². The surface area of both palms of hands is 420 cm² and the percentage of the hands contaminated during sanding is 20%. The transfer efficiency is 2% for rough sawn wood (TNsG 2008, p.102) and dermal absorption is 2% and 100% for propiconazole and IPBC, respectively.

The results of this exposure estimate are given in Table 2.7.2.4.1-2. **Systemic exposure estimates** for propiconazole and IPBC are **1.29×10^{-5}** and **1.01×10^{-3} mg/kg bw/day**, respectively.

Table 2.7.2.4.1-2: Exposure from dermal contact with treated wood

Touching of dry wood	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %
Wood contamination		
Application rate (a.s.) g/m^2	0.23	0.360.036
Application rate (a.s.) mg/cm^2	0.023	2
Percentage dislodgeable	2	7.2×10^{-4}
Dislodgeable residues mg a.s. /cm^2	4.6×10^{-4}	
Hand exposure		
Hand surface	420	420
% of hand contaminated	20	20
Hand deposit mg a.s./day	3.86×10^{-2}	6.05×10^{-2}
Dermal absorption %	2	100
Systemic exposure via dermal route mg a.s	7.73×10^{-4}	6.05×10^{-2}
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	$1.29 \times 10^{--5}$	1.01×10^{-3}

2.7.2.4.2 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. Timber off-cuts may originate from wood treated by dipping. The retention of the active substances in the wood is taken from the leaching test (0.23 g propiconazole/m² and 0.36 g IPBC/m²).

It is assumed that all active substance 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. An oral bioavailability of 86% is assumed for propiconazole. Complete (100%) bioavailability is assumed for IPBC.

The results of this exposure estimate are given in Table 2.7.2.4.2-1. **Systemic exposure estimates** for propiconazole, and IPBC are **3.16×10^{-3}** and **5.76×10^{-3} mg/kg bw/day**, respectively.

Table 2.7.2.4.2-1: Oral exposure via chewing treated wood chip

Chewing treated wood chip	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %
Concentration in wood		
Application rate (a.s.) g/m^2	0.23	0.36
Application rate (a.s.) mg/cm^2	0.023	0.036
Layer thickness cm	1.0	1.0
Retention of a.s. in wood	100	100
Concentration in wood (a.s.) mg/cm^3	0.023	0.036
Oral exposure		

Size of the wood chip cm^3 Extraction of active substance when chewing Extraction from wood mg a.s./day Oral absorption % Systemic exposure via oral route mg a.s.	16 10 0.03786 0.03165	16 10 0.058 100 0.0576
Systemic exposure Body weight kg Systemic exposure mg kg^{-1} day^{-1}	 10 3.16×10^{-3}	 10 5.76×10^{-3}

2.7.2.4.3 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 2.7.2.4.1, p.21). Accordingly, **systemic exposure estimates** for propiconazole and IPBC are **4**

82×10^{-5} and **7.54×10^{-5} mg/kg bw/day**, respectively.

Dermal route (hands – no gloves worn)

The surface area of both palms of hands is 420 cm^2 and this is the assumed transfer coefficient per day. With this assumption, dermal exposure is independent of the daily exposure duration. **Systemic exposure estimates** for propiconazole and IPBC are **1.29×10^{-5}** and **1.01×10^{-3} mg/kg bw/day**, respectively, the same as for the acute scenario.

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

An infant (10 kg body weight) is playing on playground structure outdoors. The hand surface area is 200 cm^2 and the percentage of the hands contaminated during playing is 20% (TNsG Part 3, page 5). The concentration of active substance at the wood surface is 0.023 mg propiconazole and 0.036 mg IPBC per cm^2. The transfer efficiency is taken from the TNsG 2008 (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 86% for propiconazole and 100% for IPBC.

Systemic exposure estimates for propiconazole and IPBC are **1.62×10^{-3} and 5.76×10^{-3} mg/kg bw/day**, respectively (Table 2.7.2.4.4-1).

Table 2.7.2.4.4-1: Exposure of infants via skin and hand-to-mouth transfer

Touching of dry wood and mouthing	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %
Wood contamination Application rate (a.s.) g/m^2 Application rate (a.s.) mg/cm^2 Percentage dislodgeable Dislodgeable residues mg a.s. $/cm^2$	 0.23 0.023 2 4.6×10^{-4}	 0.36 0.036 2 7.2×10^{-4}

Hand exposure		
Hand surface cm^2	200	200
% of hand contaminated	20	20
Hand deposit mg a.s./day	1.84×10^{-2}	2.88×10^{-2}
Dermal absorption %	2	100
Systemic exposure via dermal route mg a.s	3.68×10^{-4}	2.88×10^{-2}
Oral exposure		
Hand deposit mg a.s./day	1.84×10^{-2}	2.88×10^{-2}
Oral absorption %	86	100
Systemic exposure via dermal route mg a.s.	1.58×10^{-2}	2.88×10^{-2}
Systemic exposure		
Total systemic exposure a.s. mg	1.62×10^{-2}	5.76×10^{-2}
Body weight kg	10	10
Systemic exposure mg kg^{-1} day^{-1}	1.62×10^{-3}	5.76×10^{-3}

2.7.2.4.5 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 cm^2. Body contamination (without hands and feet) was calculated to be 17,140 mg for above described industrial exposure scenarios (see Table 3.2-2) are re-expressed as mg a.s./cm^2.

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 total surface of both hands would account for 1640 cm^2 (surface of hand = 820 cm^2). As another worst case assumption, 50% of the residues in the touched area are considered to be transferred to the skin. The results of the estimation are given in Table 2.7.2.4.5-1.

Systemic exposure estimates for propiconazole and IPBC are **2.06×10^{-3}** and **0.15 mg/kg bw/day**, respectively.

Table 2.7.2.4.5-1: Exposure during laundry of contaminated clothing

Laundry of contaminated clothing	**Propiconazole**	**IPBC**
active substance % (w/w)	0.20 %	0.30 %
Clothing contamination		
Actual dermal deposit (product) mg/day	17140	17140
Actual dermal deposit (a.s.) mg/day	34.28	51.42
Overall surface cm^2	22700	22700

Surface concentration mg a.s./cm^2/day	1.51×10^{-3}	2.27×10^{-3}
No of working days before washing	5	5
Percentage dislodgeable	50	50
Dislodgeable residues mg a.s./cm^2	3.78×10^{-3}	5.66×10^{-3}
Hand exposure		
Hand surface cm^2	1640	1640
Hand deposit mg a.s./day	6.19	9.29
Dermal absorption %	2	100
Systemic exposure via dermal route mg a.s	0.12	9.29
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	2.06×10^{-3}	0.15

2.7.2.4.6 Chronic phase: Adults, children and infants– inhalation of volatilised 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 and Propiconazole further have a lower 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 Propiconazole : 5.6×10^{-5} Pa (at 25°C)
• Vapour pressure IPBC : 2.36×10^{-3} Pa (at 20°C)
• Molecular weight of Propiconazole : 342.2 g/mol
• 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:
Propiconazole : 5.6×10^{-5} Pa x 1%/101324 x 106 = 5.53×10^{-6} ppm (mL/m^3)
IPBC : 2.36×10^{-3} Pa x 1%/101324 x 106 = 2.33×10^{-4} ppm (mL/m^3)

• SVC:
Propiconazole: 5.53×10^{-6} ppm x 342.2 g/mol/24.1L = 7.85×10^{-5} mg/m^3
IPBC: 2.33×10^{-4} ppm x 281 g/mol/24.1L = 2.72×10^{-3} mg/m^3

• Systemic dose:
Propiconazole
Adult: 7.85×10^{-5} mg/m3 x 1.25 m^3/h x 18 h/60 kg bw = 2.94×10^{-5} mg/kg bw/day
Child: 7.85×10^{-5} mg/m3 x 0.35 m^3/h x 18 h/15 kg bw = 3.30×10^{-5} mg/kg bw/day
Infant: 7.85×10^{-5} mg/m3 x 0.24 m^3/h x 18 h/10 kg bw = 3.39×10^{-5} mg/kg bw/day
IPBC
Adult: 2.72×10^{-3} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 1.02×10^{-3} mg/kg bw/day
Child: 2.72×10^{-3} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 1.14×10^{-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 and Propiconazole during residence time is negligible.

2.7.2.4.7 Summary of secondary exposure

The overall summary of secondary systemic exposure is given in **Table 2.7.2.4.7-1**

Table 2.7.2.4.7-1: Summary of secondary exposure

Scenario	Systemic dose [mg/kg bw/day]	
	Propiconazole	**IPBC**
Acute: sanding of treated wood, amateur	Inhalation: 8.03 x 10^{-6} Dermal: 1.29 x 10^{-5} **Total: 2.09 x 10^{-5}**	Inhalation: 1.26 x 10^{-5} Dermal: 1.01 x 10^{-3} **Total: 1.02 x 10^{-3}**
Acute: chewing treated wood chip, infant	**Oral: 3.16 x 10^{-3}**	**Oral: 5.76 x 10^{-3}**
Chronic: sanding of treated wood, professional	Inhalation: 4.82 x 10^{-5} Dermal: 1.29 x 10^{-5} **Total: 6.11 x 10^{-5}**	Inhalation: 7.54 x 10^{-5} Dermal: 1.01 x 10^{-3} **Total: 1.08** x 10^{-3}
Chronic: infant playing on playground structure outdoors and mouthing	Dermal : 3.68 x 10^{-5} Oral: 1.58 x 10^{-3} **Total: 1.62 x 10^{-3}**	Dermal: 2.88 x 10^{-3} Oral: 2.88 x 10^{-3} **Total: 5.76 x 10^{-3}**
Chronic, intermittent: adult laundering work clothes at home	**Dermal: 2.06 x 10^{-3}**	**Dermal: 0.15**
Chronic: Adults, children and infants– inhalation of volatilised residues indoors	Inhalation: Adult: 2.94 x 10^{-5} Child: 3.30 x 10^{-5} Infant: 3.39 x 10^{-5}	Inhalation: Adult: 1.02 x 10^{-3} Child: 1.14 x 10^{-3} Infant: 1.18 x 10^{-3}

2.7.2.5 Exposure to residues in food

Not applicable.

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

Industrial users involved in wood treatment by dipping are not exposed to critical doses of either active substance with the assumption that they use the PPE and that only 2 dipping cycles of 60 minutes per cycle are performed per day, a sufficient margin of exposure is maintained in all reasonable scenarios (Table 2.7.3.1).

Table 2.7.3.1-1: Risk characterisation for primary exposure

Scenario		AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Propiconazole						
Dipping, incl. handling	2 cycles	0.08	2.82×10^{-3}	3.53	8	2837
	4 cycles	0.08	5.40×10^{-3}	6.75	8	1481
Cleaning tank		0.3	1.53×10^{-3}	0.51	30	19623
IPBC						
Dipping, incl. handling	2 cycles	0.2	0.19	97.03	20	103
	4 cycles	**0.2**	**0.39**	**193.88**	**20**	**52**
Cleaning tank		0.35	9.72×10^{-2}	27.77	35	360

2.7.3.2 Risk for non-professional users and the general public

The biocidal product is not sold to non-professional users.

Regarding the secondary exposure, all the assessed scenarios reveal sufficient Margins of Exposure (Table 2.7.3.2-1). Hence, it can be concluded that the use of wood treated with MIRECIDE-TC/94 does not pose an acute or chronic health risk for humans.

Table 2.7.3.2-1: Risk characterisation for secondary exposure

Scenario		AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Propiconazole						
amateur sanding		0.3	2.09×10^{-5}	0.0070	30	1434817
infant chewing wood		0.3	3.16×10^{-3}	1.05	30	9479
professional sanding		0.08	6.11×10^{-5}	0.08	8	131037
infant on playground		0.08	1.62×10^{-3}	2.02	8	4941
laundry		0.08	2.06×10^{-3}	2.58	8	3876
inhalation volatilised residues indoors	adults	0.08	2.94×10^{-5}	0.04	8	272109
	children	0.08	3.30×10^{-5}	0.04	8	242424
	infants	0.08	3.39×10^{-5}	0.04	8	235988
IPBC						
amateur sanding		0.35	1.02×10^{-3}	0.29	35	34295
infant chewing wood		0.35	5.76×10^{-3}	1.65	35	6076
professional sanding		0.2	1.08×10^{-3}	0.54	20	18460
infant on playground		0.2	5.76×10^{-3}	2.88	20	3472
laundry		0.2	0.155	77.39	20	129
inhalation volatilised residues indoors	adults	0.2	2.94×10^{-5}	0.01	20	680272
	children	0.2	3.30×10^{-5}	0.02	20	72624
	infants	0.2	3.39×10^{-5}	0.02	20	12868

2.7.3.3 Risk for consumers via residues

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

2.8 Risk assessment for the environment

MIRECIDE-TC/94 is a water-dispersible wood preservative concentrate for industrial use. The concentrated product contains 10.3% (w/w) IPBC and 6.4% (w/w) propiconazole. The active substance IPBC was included in Annex I to directive 98/8/EC 1 July 2010 for use as product type 8 (wood preservative), through directive 2008/79/EC and the active substance propiconazole was included in Annex I 1 April 2010 for wood preservative, through directive 2008/78/EC.

The environmental risk assessment for the product MIRECIDE TC/94 is based on the active substances IPBC and propiconazole (see Assessment Report IPBC PT8, June 30, 2009 and Assessment Report propiconazole PT8, June 30, 2009).

2.8.1 Fate and distribution in the environment

There are not new studies with biocidal product. See Assessment Report IPBC PT8, June 30, 2009 and Assessment Report propiconazole PT8, June 30, 2009

2.8.2 Effects on environmental organisms

There are not new studies with biocidal product. See Assessment Report IPBC PT8, June 30, 2009 and Assessment Report propiconazole PT8, June 30, 2009

2.8.3 Environmental exposure assessment

Use classes under consideration

The applicant denotes that the product MIRECIDE TC-94 can be applied for the wood to be used up to Use Class 3 (UC3). According to CEN 335-1:2006, this class can be defined as follow: situation in which wood or wood-based product is not covered and not in contact with the ground. It is either continually exposed to the weather or is protected from the weather but subjected to frequent wetting.

Application rates

Timber treatment is conducted by dipping. The treatment of the timber is done by only one process. MIRECIDE-TC/94 is diluted in a bath of water to give a final concentration of 1 – 3% in the dipping solution. The immersion procedure of the timbers is around 1 minute. The application rates of MIRECIDE-TC/94 range from 1-3% MIRECIDE-TC/94/m^3 wood, containing 0.0309-0.092 kg IPBC/m^3 and 0.019-0.058 kg Propiconazole/m^3. The usual dose level is a solution containing 2% of Mirecide TC/94 (2.06 kg IPBC/m^3 and 1.28 kg Propiconazole/m^3). The leaching test has been performed with the usual level of product 20 kg/m^3, as this application rate is less than 2 times the maximum application rate (30 kg/m^3), a linear extrapolation can be used (Workshop. Arona, 2005). In table 2.8.3-1 intended uses, application rates and effective retentions of MIRECIDE-TC/94 are presented.

Table 2.8.3-1. Intended uses, application rate and effective retention of each active substance in wood.

Uses treatment process	Users	Application rate product (min.-max.) (g/m^3)	Number application per year/life time	Interval between applications	a.s. in treatment (min.-max.) %		Effective retention of the a.s. in wood (g/m^2)	
					IPBC	**PROP**	**IPBC**	**PROP**
UC3-Preventive Dipping process	Professional users	1-3% (w/w) of Mirecide TC/94 10,000-30,000	1	n.a.	0.103-0.309	0.064-0.192	(solution 2% of product) 0.17 **(solution 3% of product)** **0.26**	(solution 2% of product) 0.11 **(solution 3% of product)** **0.16**

PROP: propiconazole
n.a.: no apply

Emission to the environment from the use of MIRECIDE-TC/94

The environmental exposure assessment is based on the OECD series on emission scenario documents (OECD ESD) "Emission Scenario Document for Wood Preservatives (Parts 1 and 2)" (OECD, 2003[4]). Where necessary the "Technical Guidance Document (TGD) for Risk Assessment" (European Commission, 2003) is also taken into consideration. This document distinguishes three phases for which emission rates are estimated:

- The treatment process
- Storage
- Wood in services

The application is undertaken in joineries. In general, emissions to sewage water during applications in joineries are not likely to occur, because **dipping containers are stand-alone devices without direct connection to the sewage**. **Residues and waste solvents from such dipping containers will be treated as special waste and will not be discharged into the public sewage system.** Nevertheless, the OECD application and storage scenarios for dipping are considered and provided for reasons of completeness.

For the envisaged fields of use for MIRECIDE-TC/94 three main scenarios with the following sub-categories have been addressed (Table 2.8.3-2).

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

Table 2.8.3-2 Relevant exposure scenarios for use of MIRECIDE-TC/94

Main exposure scenario	Subcategory
Industrial application	- Dipping wooden articles
Industrial storage	- Dipping wooden articles
In-service leaching from treated wood	- Bridge over pond - Fence (poles with leachable planks between; 2 m high, 1 m long) - Timber cladded house (height 2.5 m, circumference is 50 m) - Noise barrier (poles with leachable planks in between; 3 m high, 1000 m long)

An overview of the scenarios and receiving compartments used is given in Table 2.8.3-3

Table 2.8.3-3 Overview of emission scenarios used for PEC estimation

Receiving compartment	Phase	Scenario
STP	Treatment process and storage	Automated dipping
(STP→ surface water) Surface water	Treatment process and storage	Automated dipping
(STP→ surface water) Surface water	Wood in service	Noise barrier (UC3) Bridge (UC3)
Soil, ground water	Storage	Automated dipping
	Wood in service	Noise barrier (UC3) Fence (UC3) House cladding (UC3)

Leaching rate

The emission scenarios for storage and wood in service require input of leaching rates of fluxes, expressed as mass loss of the active ingredient per unit of wood area per time (i.e. kg/m^2/d).

The leaching of the active substances IPBC and propiconazole from wood treated with Mirecide-TC/94 was studied in a semi-field study (Klamer and Venås, 2010). The test design is in accordance with NT Build 509 (NT method), developed by the Nordic Innovation Centre (approved 2005-03), in which wooden panels treated for hazard class 3 were subjected to outdoor exposure under natural weather conditions in Denmark.

The panels were treated by dipping in a bath containing a 2% of Mirecide-TC/94 solution. The dimensions of the wooden blocks were 25x100x760mm, corresponding with 1.93E-0.3 m^3 and 0.195 m^2 (wood area/wood volume ratio is equal to 101 m^2/m^3). The final IPBC and propiconazole retentions on the treated timber were 170 mg/m^2 and 110 mg/m^2, respectively. Exposure in the leaching study on the field was 223 days. The leachate was collected and monitored by chemical analysis (HPLC-MS). Chemical analyses were done at days 5, 12, 23, 50, 61, 145, 223 corresponding to cumulative rainfall of 9.9, 20.6, 43.7, 63.2, 103.1, 277.6, 523.0 mm, respectively.

The data has been corrected for average rainfall based on an average annual precipitation of 700 mm. The resulting corrected days of exposure were 5, 11, 23, 33, 54, 145 and 273.

The leaching values for TIME 1 (30 days) in emission scenarios for wood in service were calculated from the cumulative leaching amount at 33 days using daily average leaching amounts. Some daily average leaching amounts were used as $FLUX_{STORAGE}$ in emission scenarios for storage. For TIME2, in emission scenarios, was 15 years (Workshop. Arona, 2005). On days 11, 22 and 33, the cumulative losses of IPBC were 40.69, 47.95 and 49.94 for IPBC, respectively, and 18.2, 22.68 and 24.96 for propiconazole, respectively. Recalculated during 14 and 30 days, the amount of IPBC was 41.89 (2.99 mg IPBC/m^2/day) and 49.32 (1.64 mg IPBC/m^2/day), respectively, and the amount of propiconazole was 18.9 (1.35 mg propiconazole/m^2/day) and 24.2 (0.80 mg propiconazole/m^2/day), respectively. For TIME2 period is assumed 100% leaching. The retention of the applicant's product was 1.7 g/m^2 (using a dipping solution containing 2% of MIRECIDE TC/94) which result in a retention of 170 mg IPBC/m^2 timber and 110 mg propiconazole/m^2.

The leaching study was performed with the usual level of product 20 kg/m^3; this application rate is lower than the maximum application rate (30 kg/m^3). The application rate is less than 2 times the maximum application rate, a linear extrapolation can be used (Workshop. Arona, 2005). The leaching values were corrected with a factor of 1.5 (Table 2.8.3-4).

Table 2.8.3-4 a Leaching values corrected with a factor of 1.5

	FLUX (mg a.i/m^2/day)					
	IPBC			**Propiconazole**		
	14 days	**TIME1=30 days**	**TIME2= 15 years**	**14 days**	**TIME1=30 days**	**TIME2= 15 years**
Dipping	4.5	2.46	0.0465	2.025	1.2	0.03

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3-4 b Leaching values corrected with a factor of 2.1

	FLUX (mg a.i/m^2/day)					
	IPBC			**Propiconazole**		
	14 days	**TIME1=30 days**	**TIME2= 15 years**	**14 days**	**TIME1=30 days**	**TIME2= 15 years**
Dipping	9.45	5.166	0.098	4.25	2.52	0.063

2.8.3.1 PEC in sewage treatment plant (STP)

Losses to sewage treatment plants (STP) are calculated for the industrial application stage, and for in-service leaching from the surfaces of noise barriers (constructed from pre-treated timber). For the industrial application stage the volume of wood treated per day is set to the defaults of 100 m^3 for automated dipping. It is assumed that depending on the water solubility of the active substances (168 mg/L for IPBC and 100 mg/L for Propiconazole) a certain amount of the applied active substances (3% for both substances) (default value OCED ESD page 42) will enter to a wastewater treatment plant (STP). Furthermore, the OECD scenario "noise barrier" assumes that 70% of the emissions from wood will reach the STP. The dimensions of the STP (2000 m^3 per day) was taken from the Technical Guidance Document (TGD, Part. II, 2003). PEC_{STP} are listed in table 2.8.3.1-1.

Table 2.8.3.1-1 a PEC_{STP} values, expressed as IPBC and propiconazole, respectively, for the process, storage and barrier scenarios using MIRECIDE TC-94 (input: maximum retentions 170 mg IPBC /m^2 and 110 mg propiconazole/m^2).

Scenario	IPBC (+DEG)		PROPICONAZOLE (+DEG)	
	Time 1	Time 2	Time 1	Time 2
	PEC_{STP} (µg IPBC/l)	PEC_{STP} (µg IPBC/l)	PEC_{STP} (µg prop/l)	PEC_{STP} (µg prop/l)
Application				
Automated dipping	22.68	-	19.53	-
Wood in service				
Noise barrier TIME 2: 20 years	1.13	0.02	1	0.02

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3.1-1 b PEC_{STP} values, expressed as IPBC and propiconazole, respectively, for the process, storage and barrier scenarios using MIRECIDE TC-94 (input: maximum retentions 170 mg IPBC /m^2 and 110 mg propiconazole/m^2). Values corrected with a factor of 2.1.

Scenario	IPBC (+DEG)		PROPICONAZOLE (+DEG)	
	Time 1	Time 2	Time 1	Time 2
	PEC_{STP} (µg IPBC/l)	PEC_{STP} (µg IPBC/l)	PEC_{STP} (µg prop/l)	PEC_{STP} (µg prop/l)
Application				
Automated dipping	47.65	-	41.01	-
Wood in service				
Noise barrier TIME 2: 20 years	2.37	0.042	2.1	0.042

2.8.3.2 PEC in surface water

Industrial application and storage

For the industrial application stage it is assumed that depending on the water solubility (168 mg/L for IPBC and 100 mg/L for propiconazole) of the compounds a certain amount of the applied active

substances, 3% for both (default value OCED ESD page 42) will enter to the surface water via a wastewater treatment plant (STP). The dimensions of the STP (2000 m^3 per day) and the dilution factor (10) to the surface water were taken form the Technical Guidance Documents (TGD, Part II, 2003). In addition, knowing log K_{ow} and Henry's law constant of both active substances we can obtain the value for adsorption on sewage sludge (TGD Part II Appendix II). For propiconazole: K_{ow} = 3.7 and Henry's law constant = $9.2*10^{-5}$ $Pa*m^3*mol^{-1}$, thus, a factor of 0.21 was taken into account as a default for adsorption of propiconazole on sewage sludge default (log K_{ow} = 4, log H = -4). In the case of IPBC: K_{ow} = 2.81 and Henry's law constant = $4.92*10^{-3}$ $Pa*m^3*mol^{-1}$, thus, a factor of 0.43 was taken into account as a default for adsorption of IPBC on sewage sludge default.

For the storage stage it is assumed in the OECD scenarios that emissions from the storage place directly reach a small creek with a flow rate of 0.3 m^3 per second (= 25920 m^3/day). The refinement of PECs resulting from this summation was also considered in the light of equation 45 of TGD (Table 2.8.3.2-1).

Table 2.8.3.2-1 a Daily emission rates to the surface water and derived PEC water values for industrial application and the storage scenarios, using 20 kg MIRECIDE TC/94/m^3 for automated dipping.

Scenario	**IPBC (+DEG)**	**PROPICONAZOLE (+DEG)**
	Time 1	**Time 1**
	PEC water (µg IPBC/l)	**PEC water (µg prop/l)**
Application and storage		
Automated dipping	2.19*	1.95
Storage	0.44	0.3

*PBC, assuming complete transformation of IPBC to PBC during wastewater treatment

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3.2-1 b Daily emission rates to the surface water and derived PEC water values for industrial application and the storage scenarios, using 20 kg MIRECIDE TC/94/m^3 for automated dipping.

Scenario	**IPBC (+DEG)**	**PROPICONAZOLE (+DEG)**
	Time 1	**Time 1**
	PEC water (µg IPBC/l)	**PEC water (µg prop/l)**
Application and storage		
Automated dipping	4.599*	4.095
Storage	0.924	0.63

*PBC, assuming complete transformation of IPBC to PBC during wastewater treatment

Service-life of treated wood

During outdoor service life PECs for industrial pre-treated wood are calculated. The target compartments are pond water (scenario ´bridge over pond´) and surface water (scenario ´noise barrier´).

The OECD model "bridge over a small pond" calculates concentrations in pond water after 30 days and a longer relevant time period after application. Applying this scenario and taking into account a half-life of 0.129 days for IPBC and 6.4 days for propiconazole in the surface water. The scenario describes a wooden bridge or walkway on poles with a railing. The total surface area of the bridge considering all wooden parts is 10 m^2. The primary receiving environmental compartment is considered to be a static surface water (i.e. pond). In the frame of the ESD review project, the default value for the size of the receiving water body (Vwater) was set to 1000 m^3. This value is based on an evaluation made by the German Federal Environment Agency (UBA) showing that a ratio of bridge surface to water volume of 1:100 is realistic. Taking into account a bridge surface of 10 m^2, this results in a default value for Vwater of 1000 m^3. Applying this scenario and taking into account a half-life of 0.129 days for IPBC and 6.4 days for propiconazole in the surface water the PEC values obtained are summarized in Table 2.8.3.2-2.

The OECD model "noise barrier" assumes that 70% of the emissions from wood will reach the sewage and – via STP - the surface water. The dimensions of the wastewater treatment plant (2000 m^3 per day) and the dilution factor (10) to the surface water were taken from the Technical Guidance Document (TGD, Part II, 2003). The PEC values are summarized in Table 2.8.3.2-2.

Table 2.8.3.2-2.a Wood in service: Summary of calculated PECs (input: maximum retentions of the product in the wooden with the maximum application rate (3%): 0.25 g/m^2 for IPBC and 0.165 g/m^2 for propiconazole)

Scenario		IPBC (+DEG)		PROPICONAZOLE (+DEG)	
		Time 1	Time 2	Time 1	Time 2
		PEC water (µg IPBC/l)		PEC water (µg prop/l)	
Wood in service					
Noise barrier	**Leaching in service via STP**	0.144*	0.003*	0.0995	0.0025
Bridge over the pond	**Leaching in service via STP**	0.0046	0.00009	0.107	0.023

*PBC, assuming complete transformation of IPBC to PBC during wastewater treatment

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3.2-2.b Wood in service: Summary of calculated PECs (input: maximum retentions of the product in the wooden with the maximum application rate (3%): 0.25 g/m^2 for IPBC and 0.165 g/m^2 for propiconazole)

Scenario		IPBC (+DEG)		PROPICONAZOLE (+DEG)	
		Time 1	Time 2	Time 1	Time 2
		PEC water (µg IPBC/l)		PEC water (µg prop/l)	
Wood in service					
Noise barrier	**Leaching in service via STP**	0.302*	0.0063*	0.208	0.005
Bridge over the pond	**Leaching in service via STP**	0.009	0.0002	0.224	0.048

*PBC, assuming complete transformation of IPBC to PBC during wastewater treatment

2.8.3.3 PEC in sediment

As is stated in the Assessment Report of IPBC there are no data on sediment dwelling organisms and no specific data for the determination of PEC values for sediment. Therefore, the risk assessment for sediment is based on the equilibrium partition method which gives the same result as that for surface water (Danish CAR, 2008, p.13). The calculation of $PEC_{sediment}$ values is therefore not considered necessary.

For propiconazole, the transferred concentration in suspended sediment was calculated from mg a.i./l (water) to mg a.i./kg suspended sediment using formula 50 with the aid of formulas 23 and 24 from the TGD (2003), part II. The concentration in freshly deposited sediment was taken as the PEC for sediment, and therefore, the properties of suspended matter were used. The degradation half-life of propiconazole in the whole water-sediment system (DT_{50} of 1206 days at 12°C) was used in order to provide PECs in surface water for the calculation of PECs in suspended sediment. The propiconazole concentration in water as mg/l has to be multiplied by a factor of 21.3 to get the concentration in sediment as mg/kg wet weight. The PECs in sediment for different scenarios described under PEC in surface water are listed in Table 2.8.3.3-1.

Table 2.8.3.3-1a Summary of $PEC_{sediment}$ for propiconazole and IPBC for different scenarios.

Scenario	PROPICONAZOLE (+DEG)	
	Time 1	Time 2
	PEC sediment (µg prop/kg)	PEC sediment (µg prop/kg)
Application and storage	-	-
Automated dipping	0.0415	-
Storage	0.0064	-
Wood in service	-	-
Noise barrier TIME 2=15 years	0.0021	5E-05
Bridge over pond	0.008	0.011

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3.3-1b Summary of $PEC_{sediment}$ for propiconazole and IPBC for different scenarios.

Scenario	PROPICONAZOLE (+DEG)	
	Time 1	Time 2
	PEC sediment (µg prop/kg)	PEC sediment (µg prop/kg)
Application and storage	-	-
Automated dipping	0.087	-
Storage	0.013	-
Wood in service	-	-
Noise barrier TIME 2=15 years	0.0044	8.4E-05
Bridge over pond	0.017	0.023

2.8.3.4 PEC in air

Based on the vapour pressure (5.6 x 10^{-5} Pa×m^3 at 25°C) and the Henry`s Law constant (9.2 x 10^{-5} Pa×m^3/mol), volatilisation of propiconazole can be regarded as negligible. Calculations of the chemical lifetime in the troposphere resulted in a half life between 10.2 and 42 hours. According to these results (DT_{50} < 2 days), propiconazole is rapidly degraded by photochemical processes and no accumulation of propiconazole in air is to be expected. Therefore, calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this Product Type and proposed use patterns.

The second active substance contemplated in this risk assessment, IPBC, has a low vapour pressure of 2.36 – 4.5 x 10^{-3} Pa at 25°C combined with 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.

2.8.3.5 PEC in soil

The OECD ESD for wood in service assumes 10 cm horizontal and vertical distance in soil. However, in the EU biocides work it has been decided by the 23rd Competent Authorities meeting to consider soil volumes representing 50 cm horizontal and vertical distances in the risk assessment. All PEC calculations for in-service scenarios were carried out based on 50 cm horizontal and vertical distance.

Industrial application and storage

According to the OECD ESDs, no direct emissions to soil occur during the treatment process. Losses to air are low and deposition of the active substance to soil from air will be negligible, when compared to direct losses to soil following storage.

Emissions into soil are assumed to come from outdoor storage of the treated wood. In the OECD scenario the storage places are assumed to be unpaved and uncovered and thus have direct emissions to soil. In the calculations the dissipation half life of both substances in soil are taken into account, 129 and 0.196 days for propiconazole and IPBC, respectively. PECs after 30 days (TIME 1) are presented in Table 2.8.3.5-1

If there is risk to soil after TIME 1 in storage scenarios it is not necessary to calculate PECs in storage scenarios for TME 2 because environmental exposure from the exposure from the storages is constant. To be pragmatic the possible need for risk mitigation measures for storage prior to shipmen (impermeable pavement and/ or shelter) can be considered based on the PEC/PNEC for TIME 1.

Table 2.8.3.5-1a Losses to soil and corresponding PEC terrestrial values for treated timber in storage scenarios.

Scenario	IPBC (+DEG)	PROPICONAZOLE (+DEG)
	Time 1	Time 1
	PECsoil (µg IPBC/kgwwt)	PECsoil (µg prop/kgwwt)
Application and storage		
Application	0.01	0.36
Storage	0.01	2.1

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3.5-1 b Losses to soil and corresponding PEC terrestrial values for treated timber in storage scenarios.

Scenario	IPBC (+DEG)	PROPICONAZOLE (+DEG)
	Time 1	Time 1
	PECsoil (µg IPBC/kgwwt)	PECsoil (µg prop/kgwwt)
Application and storage		
Application	0.021	0.756
Storage	0.021	4.41

Service-life of treated wood

For assessing emissions during the outdoor service life of (hazard) class 3 wood the OECD models "fence", "timber house" and "noise barrier" are employed. The scenario "noise barrier" assumes that 30% of the emissions from wood will reach the soil.

Soil concentrations were calculated for 30 days (TIME 1) and a relevant long service-life (TIME 2) after application taking into account the soil dissipation half-life of 129 days and 0.196 for propiconazole and IPBC, respectively. PECs in soil for wood in service for 30 days (TIME 1) and after TIME 2 are summarized in table 2.8.3.5-2.

Table 2.8.3.5-2a Wood in service: Summary of calculated PECs

Scenario	IPBC (+DEG)		PROPICONAZOLE (+DEG)	
	Time 1	Time 2	Time 1	Time 2
	PECsoil (µg IPBC/kgwwt)	PECsoil (µg IPBC/kgwwt)	PECsoil (µg prop/kgwwt)	PECsoil (µg prop/kgwwt)
Wood in service				
Fence TIME 2=15 years	0.003	0.00007	0.156	0.026
House TIME 2=15 years	0.00416	0.00008	0.196	0.033
Noise barrier TIME 2=15 years	0.0015	0.00003	0.07	0.012

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.3.5-2b Wood in service: Summary of calculated PECs

Scenario	IPBC (+DEG)		PROPICONAZOLE (+DEG)	
	Time 1	Time 2	Time 1	Time 2
	PECsoil (µg IPBC/kgwwt)	PECsoil (µg IPBC/kgwwt)	PECsoil (µg prop/kgwwt)	PECsoil (µg prop/kgwwt)
Wood in service				
Fence TIME 2=15 years	0.0063	0.00015	0.33	0.054
House TIME 2=15 years	0.0087	0.00017	0.412	0.069
Noise barrier TIME 2=15 years	0.0032	0.000063	0.147	0.025

2.8.3.6 PEC in 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 day (at 12ºC)). Thus, the calculation of potential concentrations in groundwater is not considered relevant for the proposed used pattern (*cf.* IPBC CAR, p 17).

In the Finnish CA report for propiconazole, a FOCUS-PEARL-3.3.3 groundwater modelling for the compound is described, which was carried out using a worst case scenario of 35 simultaneously treated wooden houses per hectare. The calculation ware undertaken for a propiconazole release of 1000 mg/m^2 treated wood over a period of 5 years. For wood preservation use the predicted environmental concentration of propiconazole in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, were lower than the legal Drinking Water Limit of 1.0 µg/L in all FOCUS-PEARL scenarios. For the intended use of the biocide MIRECIDE-TC/94 groundwater concentrations below 0.1 µg/L can also be expected because the maximum total propiconazole release over 5 years will be 163 mg/m^2 (= total applied amount) or less. That demonstrates that the use of propiconazole in the wood preservative MIRECIDE TC/94 should not pose an unacceptable risk to groundwater.

2.8.3.7 PEC for biota (secondary poisoning)

According to TGD, part II (2003) an assessment of secondary poisoning is performed if a substance shows bioaccumulation potential and is classified with very toxic (T+), toxic (T) or harmful (Xn) with at least one of the risk phrases R48 "Danger of serious damage to health by prolonged exposure", R60 "May impair fertility", R61 "May cause harm to the unborn child", R62 " Possible risk of impaired fertility", R63 "Possible risk of harm to the unborn child", R64 "May cause harm to breastfed babies" or if there are other indications (e.g.) endocrine disruption.

IPBC reveals a log Kow of 2.81 showing that the risk for bioaccumulation of the substance to man via the food chain is low.

Although the log Kow of propiconazole (log Kow = 3.7) reveal a slight potential for bioaccumulation, the compound is not considered to be bioaccumulative according to the Finnish CAR and an assessment of secondary poisoning is not conducted.

2.8.4 Risk Characterisation for the environment

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 MIRECIDE-TC/94 containing 10.3% (w/w) IPBC and 6.4% (w/w) propiconazole. Timber treatment is conducted by dipping. MIRECIDE-TC/94 is diluted during the treatment process to give a final concentration of 1-3% in the dipping solution. All calculations are based on the highest intended retentions proposed by the participant during evaluation (26.53 g/m^3 of propiconazole and 16.48 g/m^3 of IPBC). The calculated PEC/PNEC ratios are provided for the STP, the aquatic environment and the terrestrial compartment in the following chapters.

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

2.8.4.1 Aquatic compartment (incl. sediment)

2.8.4.1.1 PNEC derivation for surface water, sediment and STP

In Documents IIA of the dossiers of the active substances the following PNEC values were derived for IPBC, PBC and propiconazole, which were used as basis for the risk characterisation for the STP, surface water and sediment:

Table 2.8.4.1.1 PNEC for aquatic compartment

	IPBC	PBC	Propiconazole
$PNEC_{stp}$(µg/l)	440	-	1000
$PNEC_{surface\ water}$(µg/l)	0.5	41.3	1.6
$PNEC_{sediment}$(mg/kg wwt)	*	-	0.054

*The risk for the sediment compartment due to IPBC is deduced to be the same as that assessed for surface water. Since this argumentation is in line with the Danish CAR (2008, p.13) the calculation of $PEC_{sediment}$ values is not considered necessary

2.8.4.1.2 PEC/ PNEC ratios for surface water, sediment and STP

- **STP**

Industrial application and storage

For the industrial scenario (dipping) emission to the STP was calculated in section 2.8.3.1. However, direct emissions of IPBC and propiconazole to sewage water are not expected as a general rule since industrial plants often have no direct connection to a STP. Residues from industrial uses of IPBC and propiconazole are generally recovered and treated as hazardous waste. The exposure and risk assessment for the STP was performed only for the purpose of completeness.

Service-life of treated wood

According to the OECD Emission Scenarios (OECD 2003)[5] emission to the STP are only relevant for the noise barrier scenario due to leaching from treated wood. It is assumed that noise barriers are installed on roadsides. Following precipitation, leaching to drains and consequently emissions to a

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

STP may occur. In the noise barrier scenario a default value of 70% is given, expressing the fraction of the active substance that might enter the STP due to leaching.

The calculated PEC/PNEC ratios of IPBC and propiconazole for a STP are presented in Table 2.8.4.1.2-1**.** The results show that the requirements for acceptable risk according to the TGD on Risk Assessment are met for the industrial application as well as for treated wood in service. The PEC/PNEC ratios for both active substances are far below the trigger value of 1. No risk is posed to micro-organisms in the waste water treatment process by the use of IPBC and propiconazole as active ingredients in the wood preservative MIRECIDE-TC/94.

Table 2.8.4.1.2-1a: Summary of IPBC and propiconazole PEC/PNEC-ratios resulting from industrial application and in-service leaching emissions to a local sewage treatment plant (STP)

SCENARIO		PEC_{STP} (µg/l)		$PNEC_{STP}$ (µg/l)	PEC/PNEC	
		IPBC[1)]	propiconazole		IPBC	propiconazole
Dipping		22.68	19.53	IPBC: 440 propiconazole:1000	0.0515	0.0195
Noise Barrier	30 days	1.13	1		0.0026	0.001
	15 years	0.02	0.02		0.000045	0.00002

[1)] According to the CA report for IPBC, the STP risk assessment is based on IPBC influent concentrations with no removal/degradation or translocation processes taken into consideration.

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.4.1.2-1b: Summary of IPBC and propiconazole PEC/PNEC-ratios resulting from industrial application and in-service leaching emissions to a local sewage treatment plant (STP)

SCENARIO		PEC_{STP} (µg/l)		$PNEC_{STP}$ (µg/l)	PEC/PNEC	
		IPBC[1)]	propiconazole		IPBC	propiconazole
Dipping		47.63	41.013	IPBC: 440 propiconazole:1000	0.11	0.041
Noise Barrier	30 days	2.37	2.1		0.0054	0.0021
	15 years	0.042	0.042		0.000094	0.000042

[1)] According to the CA report for IPBC, the STP risk assessment is based on IPBC influent concentrations with no removal/degradation or translocation processes taken into consideration.

- **Surface water**

Industrial application and storage

For the industrial uses of IPBC and propiconazole in the wood preservative MIRECIDE-TC/94 two emission pathways to surface waters are relevant: The active substances may enter surface water either via an STP due to emissions at the application stage or by run-off from on-site stored pre-treated timber.

For the industrial application stage it is assumed that depending on the water solubility of the compound a certain amount of the applied active substance (3%) will enter the surface water via a wastewater treatment plant. The dimensions of the wastewater treatment plant (2000 m³ per day) and

the dilution factor (10) to the surface water were taken from the Technical Guidance Document (TGD, Part II, 2003).

For the storage stage it is assumed in the OECD scenarios that emissions from the storage place directly reach a small creek with a flow rate of 0.3 m^3 per second (= 25920 m^3/day).

Service-life of treated wood

According to the ESD (OECD 2003), emissions to the aquatic compartment may occur indirectly via STP due to leaching from a noise barrier. Direct intake can take place considering a treated bridge over pond.

The OECD scenario "bridge over a small pond" calculates concentrations in pond water after 30 days and a longer relevant time period based on the leaching. In the calculation the dissipation half-lifes of the active substances in water (6.4 days) are taken into account. In fact, both degradation and adsorption is taken into account when using a dissipation half-life. PECs in surface water for wood in service for 30 days (TIME 1) and after TIME 2 are summarized in Table 2.8.3.2-2.

The OECD scenario "noise barrier" assumes that 70% of the emissions from wood will reach the sewage and – via STP - the surface water. The dimensions of the wastewater treatment plant (2000 m^3 per day) and the dilution factor (10) to the surface water were taken from the Technical Guidance Document (TGD, Part II, 2003).

Emissions resulting from IPBC in the product are considered to enter surface water as PBC residues, when the intake proceeds via sewage treatment plants. In this case, the IPBC influent concentration in the STP is converted into PBC, employing the molecular weight ratio. In a second step, the distribution of PBC during wastewater treatment between the water phase, sludge and air has been conducted following the Simple Treat recommendations. Hence, surface water residues emitted via STP are considered to be present as PBC. In contrast, the risk assessment for surface water bodies following direct emissions (e.g., in the bridge over pond scenario) is based on the parent compound IPBC itself.

For the different scenarios refined PEC values were used for the risk characterisation, including dilution in the receiving water body as well as degradation of IPBC, PBC and propiconazole in the aquatic environment (see section 2.8.3.2 for details).

In Table 2.8.4.1.2-2 the PEC/PNEC ratios for the different scenarios are summarised.

The results show that for IPBC and its metabolite PBC the requirements for acceptable risk according to the TGD on Risk Assessment are met for all scenarios. PEC/PNEC ratios are below the trigger value of 1. For propiconazole the PEC/PNEC ratio for the in-service leaching in the "bridge over pond" scenario is above the trigger value of 1 after a time period of 30 days.

Table 2.8.4.1.2-2a: Summary of IPBC, PBC and propiconazole PEC/PNEC ratios for surface water

SCENARIO			PEC surface water (µg/L)		PNEC surface water (µg/L)	PEC/ PNEC	
			IPBC/ PBC	prop.		IPBC/ PBC	prop.
Dipping	Application via STP		2.196*	1.95	IPBC: 0.5	0.054+	1.2
	Storage		0.44	0.3		0.880	0.188
Noise Barrier	Leaching in- service via STP after dipping	30 days	0.144*	0.1	PBC: 41.3	0.004+	0.063
		15 years	0.003*	0.002		0.00002+	0.001
Bridge over pond	Leaching in service after dipping	30 days	0.23	5.32	prop.: 1.6	0.460	**3.325**
		15 years	0.005	0.139		0.009	0.087

* PBC; assuming complete transformation of IPBC to PBC during the waste water treatment process
+ PEC/PNEC ratio for PBC
prop = propiconazole

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.4.1.2-2b: Summary of IPBC, PBC and propiconazole PEC/PNEC ratios for surface water

SCENARIO			PEC surface water (µg/L)		PNEC surface water (µg/L)	PEC/ PNEC	
			IPBC/ PBC	prop.		IPBC/ PBC	prop.
Dipping	Application via STP		4.61*	4.09	IPBC: 0.5	0.113+	2.52
	Storage		0.92	0.63		**1.84**	0.39
Noise Barrier	Leaching in- service via STP after dipping	30 days	0.302*	0.21	PBC: 41.3	0.0084+	0.132
		15 years	0.006*	0.004		0.00004+	0.0021
Bridge over pond	Leaching in service after dipping	30 days	0.48	11.172	prop.: 1.6	0.966	**6.48**
		15 years	0.010	0.29		0.02	0.182

* PBC; assuming complete transformation of IPBC to PBC during the waste water treatment process
+ PEC/PNEC ratio for PBC
prop = propiconazole

- **Sediment**

The risk for the sediment compartment due to IPBC is deduced to be the same as that assessed for surface water. Since this argumentation is in line with the Danish CAR (2008, p.13) the calculation of $PEC_{sediment}$ values is not considered necessary.

Industrial application and storage

For the industrial uses of propiconazole in the wood preservative MIRECIDE-TC/94 two emission pathways to sediment are relevant: The active substance may enter surface water either via an STP due to emissions at the application stage or by run-off from on-site stored pre-treated timber.

Service-life of treated wood

In order to asses the risk for sediment dwelling organisms due to in-service leaching of propiconazole, the "bridge over pond" scenario and the "noise barrier" scenario as described in the ESD for PT8 (OECD 2003) were evaluated.

In Table 2.8.4.1.2-3 the PEC/PNEC ratios for propiconazole in the different scenarios are summarised. The results show that only for the "bridge over pond" scenario PEC/PNEC ratios are above the trigger value of 1. The requirements for acceptable risk according to the TGD on Risk Assessment are met for the leaching in service scenario "noise barrier" and the application and storage scenario.

Table 2.8.4.1.2-3a: Summary of propiconazole PEC/PNEC ratios for the sediment

SCENARIO			**$PEC_{sed.}$ (mg/kg wwt) propiconazole**	**$PNEC_{sed}$ (mg/kg wwt)**	**PEC/ PNEC propiconazole**
Dipping	Application via STP		0.0415	0.054	0.769
	Storage		0.0064		0.119
Noise Barrier	Leaching in- service via STP after dipping	30 days	0.0021		0.039
		15 years	0.00005		0.001
Bridge over Pond	Leaching in service after dipping	30 days	0.38		**7.037**
		15 years	0.548		**10.148**

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.4.1.2-3b: Summary of propiconazole PEC/PNEC ratios for the sediment

SCENARIO			$PEC_{sed.}$ (mg/kg wwt) propiconazole	$PNEC_{sed}$ (mg/kg wwt)	PEC/ PNEC propiconazole
Dipping	Application via STP		0.087	0.054	**1.61**
	Storage		0.013		0.249
Noise Barrier	Leaching in- service via STP after dipping	30 days	0.004		0.0819
		15 years	0.0001		0.0021
Bridge over Pond	Leaching in service after dipping	30 days	0.798		**14.77**
		15 years	1.15		**21.31**

2.8.4.1.3 Risks characterisation for groundwater used as drinking water

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).

In the Finnish CA report for propiconazole, a FOCUS-PEARL-3.3.3 groundwater modelling for the compound is described, which was carried out using a worst case scenario of 35 simultaneously treated wooden houses per hectare. The calculations were undertaken for a propiconazole release of 1000 mg/m^2 treated wood over a period of 5 years. For wood preservation use the predicted environmental concentration of propiconazole in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, were lower than the legal Drinking Water Limit of 0.1 µg/l in all FOCUS-PEARL scenarios. For the intended use of the biocide MIRECIDE-TC/94 groundwater concentrations below 0.1 µg/l can also be expected because the maximum total propiconazole release over 5 years will be 110 mg/m^2 (= total applied amount) or less. This demonstrates that the use of propiconazole in the wood preservative MIRECIDE-TC/94 should not pose an unacceptable risk to groundwater.

2.8.4.2 Atmosphere

Based on the vapour pressure (5.6 x 10^{-5} Pa×m^3 at 25°C) and the Henry`s Law constant (9.2 x 10^{-5} Pa×m^3/mol), volatilisation of propiconazole can be regarded as negligible. Calculations of the chemical lifetime in the troposphere resulted in a half life between 10.2 and 42 hours (*cf.* Document II-A). According to these results (DT_{50} < 2 days), propiconazole is rapidly degraded by photochemical processes and no accumulation of propiconazole in air is to be expected. Therefore, calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this Product Type and proposed use patterns.

The second active substance contemplated in this risk assessment, IPBC, has also a low vapour pressure of 2.36 – 4.5 x 10^{-3} Pa at 25°C (Henry`s Law constant of 3.38 – 6.45 x 10^{-3} Pa×m^3/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 to be persistent in air (as stated in the Danish CAR). Thus no assessment for a possible risk of the atmosphere (PEC_{air}) is conducted.

2.8.4.3 Terrestrial compartment

2.8.4.3.1 PNEC derivation for soil organisms

In Document IIA of the dossier of the active substance the following PNEC value was derived for IPBC and propiconazole:

Table 2.8.4.3.1 PNEC for soil compartment

	IPBC	**Propiconazole**
$PNEC_{soil}$(mg/kg wwt)	0.005	0.100

The risk assessments for the soil compartment are calculated on the basis of these PNECs and the PECs for soil as calculated in the exposure assessment (see section 2.8.3.5).

2.8.4.3.2 PEC/PNEC ratios for soil

Industrial application and storage

For the industrial use of IPBC and propiconazole in the wood preservative MIRECIDE-TC/94 emissions to soil are only possible during on-site storage of pre-treated timber. It is assumed that half of the emissions from a storage place will leach into the non-covered ground.

Service-life of treated wood

For use (hazard) class 3 outdoor service life the OECD models “fence“, “timber house” and “noise barrier” were used. The OECD model “noise barrier” assumes that 30 % of the emissions from wood will reach the soil. The PEC calculation for the actives takes into account degradation processes in soils.

In Table 2.8.4.3.2 PEC/PNEC ratios for the different scenarios and the two active ingredients are summarised.

Concerning the application and storage scenarios only the propiconazole PEC/PNEC ratio for the storage place is above the trigger value of 1 after the long-term storage period. This indicates that risk mitigation measures are necessary to prevent unacceptable risks to soil organisms. To avoid losses to soil the treated wood should be stored in a sheltered installation or the storage place should be furnished with a paved ground. Water from the paved storage place should be treated in an industrial sewage treatment plant or should be collected for disposal.

For in service leaching PEC/PNEC ratios for IPBC are below the trigger value of 1 in all scenarios, however for propiconazole they are above 1 in all scenarios except for the noise barrier scenario. This demonstrates that no unacceptable risk at medium and long term for soil organisms is expected to occur due to in service leaching of wood treated with the biocide MIRECIDE-TC/94.

Table 2.8.4.3.2a: **Summary of IPBC and propiconazole PEC/PNEC ratios for soil.**

SCENARIO				PEC_{soil} (mg/kg wwt)		PNEC soil (mg/kg wwt)	PEC/ PNEC	
				IPBC	prop.		IPBC	prop.
Dipping	Storage		30 days	0.01	0.36	IPBC: 0.005 Prop.: 0.100	2	**3.6**
			15 years	0.01	2.1		2	**21**
Fence	Leaching in service after dipping		30 days	0.0033	0.156		0.66	**1.56**
			15 years	0.00007	0.026		0.014	0.26
House	Leaching in service after dipping		30 days	0.0042	0.196		0.832	**1.96**
			15 years	0.00008	0.033		0.016	0.33
Noise Barrier	Leaching in service after dipping		30 days	0.0015	0.07		0.3	0.7
			15 years	0.00003	0.012		0.006	0.12

In order to harmonise both the efficacy study and the environmental exposure, all the values obtained from the environmental exposure will be multiplied for 2.1 since the retention in the leaching study is 84 g/m^2 while the retention in the efficacy study is 180 g/m^2.

Table 2.8.4.3.2b : **Summary of IPBC and propiconazole PEC/PNEC ratios for soil.**

SCENARIO				PEC_{soil} (mg/kg wwt)		PNEC soil (mg/kg wwt)	PEC/ PNEC	
				IPBC	prop.		IPBC	prop.
Dipping	Storage		30 days	0.021	0.756	IPBC: 0.005 Prop.: 0.100	**4.2**	**7.56**
			15 years	0.021	4.41		**4.2**	**44.1**
Fence	Leaching in service after dipping		30 days	0.007	0.327		**1.38**	**3.27**
			15 years	0.00015	0.054		0.029	0.54
House	Leaching in service after dipping		30 days	0.0088	0.411		**1.74**	**4.11**
			15 years	0.00017	0.069		0.033	0.69
Noise Barrier	Leaching in service after dipping		30 days	0.003	0.147		0.63	**1.47**
			15 years	0.00006	0.025		0.0126	0.252

2.8.4.4 Non compartment specific exposure relevant to food chain (primary and secondary poisoning)

According to the TGD (EC, 2003) the calculation of a possible risk to man via the food chain (PECoralpredator) should be conducted if the active substance shows a potential for bioaccumulation, indicated by a log Kow value >3.

IPBC reveals a log Kow of 2.81 indicating that no risk for bioaccumulation of the substance to man via the food chain is given.

Although the log Kow of propiconazole (log Kow = 3.7) reveals a slight potential for bioaccumulation, an assessment of secondary poisoning is not requested in the Finnish CAR (2007, p.18) for the use of propiconazole in wood preservatives.

2.8.4.5 PBT assessment

IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test and the half-life values of IPBC in fresh-water and fresh-water sediment are lower than 40 days and 120 days respectively. Therefore, the P criterion is not fulfilled.

The bioaccumulation potential is not significant based on a log Pow value of 2.8. Therefore, the B criterion is not fulfilled. The NOEC value for algae, the most sensitive aquatic species, is 0.0046 mg/l. Therefore, the T criterion is fulfilled. Thus IPBC does not fulfil the PBT or vPvB criteria.

Propiconazole is not readily biodegradable but the half-life values in fresh-water and fresh-water sediment are lower than 40 days and 120 days respectively. Therefore, the P criterion is not fulfilled.

The bioaccumulation potential is not significant based on a log Pow value of 3.72. Therefore, the B criterion is not fulfilled.

The NOEC value for algae, the most sensitive aquatic species, is 0.016 mg/l. Therefore, the T criterion is not fulfilled. Thus propiconazole does not fulfil the PBT or vPvB criteria.

2.9 Measures to protect man, animals and the environment

Methods and precautions concerning handling and use
Read attached instructions before use.
Aerate adequately the place where the product is applied.
Personal protection equipment:
Respiratory tract: Approved face mask with organic vapor filter, if the operating conditions make it advisable.
Hand protection: Suitable gloves.
Eye protection: Safety glasses
Skin protection: Use proper equipment to protect the whole body in case of accidental product splash.
General protective and hygiene measures: Do not eat, drink or smoke during handling. Change clothing after handling.

Methods and precautions concerning storage
Store in cool, ventilated places, away from the sun, heat and sources of ignition. Keep the product in its original containers tightly closed and away from ignition sources, heat and incompatible material. Avoid storage temperatures above 40 °C and below 0 °C.

Methods and precautions concerning transport
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. See Safety Data Sheet

Methods and precautions concerning fire
In case of fire, use water spray, chemical powder or foam.
Do not use water jet.
Special exposure hazards: 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.

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

Poisoning may cause:

- Irritation of the eyes, skin, mucous membranes, respiratory and gastrointestinal tract. Allergic skin reaction and sensitization

Basic first aid procedures:

- Move the person away from the contaminated Area.
- Remove contaminated or spattered clothing.
- If contact in eyes, rinse with plenty of water for 15 minutes. Do not forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing.
- If swallowed, do not induce vomiting, unless told to do so by poison control or a health care professional.
- Keep the patient at rest and maintain the body temperature.
- Check the breath. If necessary, give artificial respiration.
- If the person is unconscious, turn the patient sideways, with the head at lower than the rest of the body and the knees bended.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISONED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment

IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Emergency measures to protect the environment

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.

Do not allow spill to enter drains, sewers, conduits, basements and subsoil.

Waste management

Instructions for safe disposal of the product and its packaging:
Examine possibilities for re-utilisation.
Vigorously rinsing is required three times, or by pressing device each product container is emptied to prepare the dilution water and pour the dip tank. Do not empty into drains. Package product wastes. Close and label the waste receptacles and, likewise, any uncleaned empty containers. Dispose of them at a suitable waste incineration plant in accordance with the official regulations. When unclean empty containers are passed on, the recipient must be warned of any possible hazard that may be caused by residue

3 Proposal for decision

MIRECIDE-TC/94 is a water-dispersible wood preservative concentrate that contains 10.3% (w/w) IPBC and 6.4% (w/w) propiconazole. It is intended for industrial use and timber treatment is conducted by automated dipping.

The product is found efficient against blue stain fungi and mould when applied at a use concentration of 2-3% for green wood/fresh wood in sawmill.

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

The risk for human health of professional users through the direct use of MIRECIDE-TC/94 for the intended uses has been evaluated and its use does not pose an unacceptable risk to human health if **no more that two dipping cycles of 60 minutes are performed per day.** Regarding the risk for human health of the general public through indirect exposure to MIRECIDE-TC/94, it is also acceptable.

The risk for the environment for the intended uses of MIRECIDE-TC/94 has been evaluated considering relevant emission scenarios (industrial application, industrial storage and in-service leaching from treated wood to be used up to Use Class 3 according to CEN 335-1:2006). The overall conclusion is that MIRECIDE-TC/94 does not pose an unacceptable risk to the sewage treatment plant, soil, air and groundwater compartments. An unacceptable risk is however identified for the sediment and surface water, and specific restrictions on the use of the product are required to reduce the risk for the environment.

The Spanish CA authorises the biocidal product MIRECIDE-TC/94 as a wood preservative for fresh wood (PT 8), against blue stain fungi and mould for industrial users by automated dipping.

Particular Conditions

The biocidal product under PT8 Wood preservatives MIRECIDE-TC/94 contains 10.3% (w/w) IPBC and 6.4% (w/w) propiconazole.

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

IPBC: 980 g/kg

Propiconazole: 930 g/kg

Only two dipping cycles of 60 minutes per cycle can be performed per day, with an application rate of 2-3%.

Only for industrial application of the product by immersion, in wood or wood-based products for internal uses (Use Classes 1 and 2 as defined in CEN standard EN 335-1:2006), and in wood or wood-based products which are not under cover and not in contact with the ground, but they are protected from the weather (Use Class 3.1 as defined in CEN standard EN 335-1:2006).

It will be allowed the industrial application of the product by immersion, in wood or wood-based products which are not under cover, not in contact with the ground and unprotected from the weather (use class 3.2 to the UNE-EN 335), provided that the leachate is collected and enters a sewage treatment plant.

During industrial application, direct emissions to the sewage water are not allowed and any losses (including from the cleaning of the equipment) should be collected and reused or treated as hazardous waste.

Freshly treated timber must be stored after treatment under shelter or on impermeable hardstanding to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

In situations where treated timber would be exposed to weathering, the product must always be overcoated after drying by application of appropriate triazole-free topcoat product.

Expiry Date of the Authorisation:

The authorisation of the product MIRECIDE-TC/94 expires on 31st of March 2020, which is the expiry date of Annex I listing of the active substance propiconazole.

ADDENDUM (MARCH 2021)

NA (BC-BN030663-43): February 2017: the classification and labelling was modified because of the new classification of the active substance IPBC was included in 6th ATP of CLP Regulation

NA-AAT (BC-ED057447-47): February 2020: the expiration date was modified taking into account the extension of the approval of the active substance.

NA-MIC (BC-ST050725-08): December 2020: was submitted by the applicant regarding a change of composition in the co-formulants. The content of active substances is not changed. Please, see confidential PAR in order to check the changes. No new studies were submitted. The changes in the composition do not affect the toxicological classification.

Annexes:

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

Summary of product characteristics for a biocidal product

MIRECIDE-TC/94

Product type(s) [08]

ES/AA-2012-08-00043

ES-0001560-0000

Table of Contents

1. Administrative information

1.1. Trade name(s) of the product

Trade name(s)[6]	MIRECIDE-TC/94

1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratorios Miret, S.A.
	Address	C/. Géminis, 4 08228 – Terrassa calidad@lamirsa.com
Authorisation number	ES/AA-2012-08-00043	
Suffixes to the authorisation number linked to trade names[7]	-	
R4BP asset reference number	ES-0001560-0000	
Date of the authorisation	19/10/2012	
Expiry date of the authorisation	30/10/2025	

1.3. Manufacturer(s) of the product

Name of manufacturer	Laboratorios Miret, S.A.
Address of manufacturer	C/. Géminis, 4 08228 - Terrassa
Location of manufacturing sites	-

1.4. Manufacturer(s) of the active substance(s)

Active substance	IPBC (3-Iodo-2-propynyl butyl carbamate)
Name of manufacturer	IPBC Task Force (ISP)
Address of manufacturer	LIndestrasse10 CH-6340 Baar (Switzerland)
Location of manufacturing sites	-

Active substance	Propiconazole (1H-1,2,4-Triazole, 1-[[2-(2,4-dichloro phenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-
Name of manufacturer	Syngenta Crop Protection

[6] In case the product would have more than one name, all names can be provided in this field.

[7] Where relevant for the Member State delivering a national authorisation. Insert rows as necessary.

Address of manufacturer	Schwarzwaldallee, 215 CH – 4002 – Basle (Switzerland)
Location of manufacturing sites	-

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
IPBC	3-Iodo-2-propynyl butyl carbamate	Active substance	55406-53-6	259-627-5	10.3
Propiconazole	1H-1,2,4-Triazole, 1-[[2-(2,4-dichloro phenyl)-4-propyl-1,3-dioxolan-2-yl] methyl	Active substance	60207-90-1	262-104-4	6.4

2.2. Type of formulation

Liquid

3. Hazard and precautionary statements[8]

Hazard statements	H315: Causes skin irritation H317: May cause an allergic skin reaction H318: Causes serious eye damage H360D May damage the unborn child H372: Causes damage to organs through prolonged or repeated exposure (larynx). H410: Very toxic to aquatic life with long lasting effects

[8] According to Regulation (EC) 1272/2008, or where relevant, Directive 1999/45/EC. This section shall only include precautionary statements triggered by the CLP legislation. In accordance with paragraph 8 of document CA-May13-Doc.5.4, a precautionary statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Precautionary statements	P102: Keep out of reach of children P262: Do not get in eyes, on skin, or on clothing P280: Wear protective gloves/protective clothing/eye protection/face protection P403+P233: Store in a well-ventilated place. Keep container tightly closed P501: Dispose of contents/containers to hazardous waste facilities in accordance with national regulations.

4. Authorised use(s)

4.1. Use description[9]

Table 3. Use # 1 – Wood preservative – fungi for green wood sawmill - Automated dipping - Trained professional users

Product Type	PT8 – wood preservative
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	The biocidal product MIRECIDE-TC/94 is effective against a variety of fungal species, e.g. blue stain fungi (*Aureobasidium pullulans, Sclerophoma pityophila*), sapstainers and wood rotting fungi and against moulds (*Aspergillus niger, Penicillium citrinum, Alternaria alternata*) for green wood in sawmill
Field(s) of use	Industrial use
Application method(s)	Automated dipping
Application rate(s) and frequency	Application rate of 2-3%. Two dipping cycles of 60 minutes per cycle can be performed per day
Category(ies) of users	Trained professional user
Pack sizes and packaging material	Drums of 25, 60 and 230 L containing 25, 55 and 200 kg respectively and a container of 1000 L containing 950 kg. All of them are high density polyethylene (HDPE) container.

4.1.1. Use-specific instructions for use[10]

See point 5.1

4.1.2 Use-specific risk mitigation measures

See point 5.2

[9] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a single biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

[10] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See point 5.3

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See point 5.4

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See point 5.5

5. General directions for use[11]

5.1. Instructions for use

Read attached instructions before use. The labelling of the product shall be including the sentence: Use biocides safely. Always read the label and product information before use Aerate adequately the place where the product is applied

5.2. Risk mitigation measures

Only two dipping cycles of 60 minutes per cycle can be performed per day, with an application rate of 2-3%. The biocidal product cannot be used in wood where food or feed can be stored. Only for industrial application of the product by immersion, in wood or wood-based products for internal uses (Use Classes 1 and 2 as defined in CEN standard EN 335-1:2006), and in wood or wood-based products which are not under cover and not in contact with the ground, but they are protected from the weather (Use Class 3.1 as defined in CEN standard EN 335-1:2006). It will be allowed the industrial application of the product by immersion, in wood or wood-based products which are not under cover, not in contact with the ground and unprotected from the weather (use class 3.2 to the UNE-EN 335), provided that the leachate is collected and enters a sewage treatment plant. During industrial application, direct emissions to the sewage water are not allowed and any losses (including from the cleaning of the equipment) should be collected and reused or treated as hazardous waste. Freshly treated timber must be stored after treatment under shelter or on impermeable

[11] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

hardstanding to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

In situations where treated timber would be exposed to weathering, the product must always be overcoated after drying by application of appropriate triazole-free topcoat product.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Poisoning may cause:

- Irritation of the eyes, skin, mucous membranes, respiratory and gastrointestinal tract. Allergic skin reaction and sensitization

Basic first aid procedures:

- Move the person away from the contaminated Area.
- Remove contaminated or spattered clothing.
- If contact in eyes, rinse with plenty of water for 15 minutes. Do not forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing.
- If swallowed, do not induce vomiting, unless told to do so by poison control or a health care professional.
- Keep the patient at rest and maintain the body temperature.
- Check the breath. If necessary, give artificial respiration.
- If the person is unconscious, turn the patient sideways, with the head at lower than the rest of the body and the knees bended.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISONED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment

IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

5.4. Instructions for safe disposal of the product and its packaging

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

The biocidal product is stable for 24 months.

6. Other information

Trained professional users (TP): pest control operators and industrial users, having received specific training in this item according to the national legislation in force Royal Decree 830/2010

Annex 2: List of studies reviewed

List of <u>new data</u>[12] submitted in support of the evaluation of the active substance

IPBC

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
A4.2d/01	Study No.: B49443; Doc.-No. 433-002	Düsterloh, K.	2008	Development and Validation of a Residue Analytical Method for the Determination of IPBC and its metabolite PBC in Body Fluids and Tissue, Itingen, Switzerland: RCC,	European Union IPBC Task Force (Arch Chemicals, Dow Benelux BV, ISP Switzerland GMBH, Lanxess Deutschland GmbH and Troy Corporation)	X	☐	X	☐

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Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No

12 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	
B5.10_01	11064-2-a(M1)	Munné, O. & Maiora, M.	2010	Wood preservatives: Determination of the fungicidal effectiveness of Mirecide-TC/94 for green wood sawmill. Field test.	Laboratorios Miret, S.A. (LAMIRSA)		X	X	
B6.1.1_01	100257	Allingham, P.	2010	Acute Oral Toxicity (Acute Toxic Class Method) with MIRECIDE-TC/94	Laboratorios Miret, S.A. (LAMIRSA)		X	X	
B6.1.1_02	100259	Allingham, P.	2010	Acute Dermal Toxicity (Fixed Dose Procedure) with MIRECIDE-TC/94	Laboratorios Miret, S.A. (LAMIRSA)		X	X	
B6.2.1_01	101116	Ahuja, Varun	2010	Acute Dermal Irritation with MIRECIDE-TC/94	Laboratorios Miret, S.A. (LAMIRSA)		X	X	
B6.2.2_01	100260	Ahuja, Varun	2010	Acute Eye Irritation/Corrosion with MIRECIDE-TC/94	Laboratorios Miret, S.A. (LAMIRSA)		X	X	
B3.8.01	55709350	Fieseler A.	2010	Determination of Persistent Foaming of MIRECIDE-TC/94 on dilution with water	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.4.03	55703190	Fieseler A.	2010	Determination of Pyrophoric Properties of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.1.01	55701203	Fieseler	2010	Determination of the physical state, colour and odour of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.4.01	55702189	Fieseler	2010	Determination of the Flash Point of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.4.02	20100269.01	Dornhagen	2010	Determination of the Temperature of Self-Ignition of Volatile Liquids and of Gases.Auto-Flammability A.15	Laboratorios Miret S.A. (LAMIRSA)		X	X	

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B.3.4.04	55704207	Fieseler	2010	Determination of the Flammability of MIRECIDE-TC/94 in contact with water	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.5.01	55705352	Fieseler	2010	Determination of the pH-Value of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.6.01	55706182	Fieseler	2010	Determination of the Relative Density of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.10.01	55707184	Fieseler	2010	Determination of the Surface Tension of an Aqueous Solution of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.10.02	55708196	Fieseler	2010	Determination of the Viscosity of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.7.03	55713204	Meinerling and Herrmann	2012	Determination of the Storage Stability Long Term of MIRECIDE- TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.7.01	555712204	Meinerling and Herrmann	2010	Determination of the Accelerated Storage Stability of MIRECIDE-TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.7.02	55714204	Meinerling and Herrmann	2010	Determination of the Low Temperature Stability of MIRECIDE- TC/94	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B.3.8.05	13_01721-a	Tecnalia	2013	Emulsion characteristics and re-emulsification properties	Laboratorios Miret S.A. (LAMIRSA)		X	X	
B7.1		Klamer, M. and Venas, T.M	2000	Semi field leaching study Danish Technological Institute, Wood and Textile, Project 1006657-17, Order No.: 349742	Laboratorios Miret, S.A. (LAMIRSA)		X	X	

Annex 3: Analytical methods residues – active substance

IPBC and Propiconazole

Matrix, action levels, relevant residue and reference

IPBC

Matrix	limit	relevant residue	reference or comment
plant products		Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials.	
food of animal origin		Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials.	
Soil		HPLC-MS/MS, LOQ = 0.01 mg/kg	
drinking water		Both for surface water, ground water and drinking water. HPLC-MS/MS, LOQ = 0.1 µg/L	
surface water		HPLC-MS/MS, LOQ = 0.1 µg/L	
Air		Not necessary, IPBC is not volatile and spray applications only involve non-respirable particles .	
body fluids / tissues		Relevant residues for monitoring human body fluid and tissues were PBC and IPBC. In blood and muscle IPBC degraded rapidly (to PBC) and it was not possible to determine IPBC residues above 70%. Analysis was done by HPLC using reversed-phase liquid chromatography and a water / methanol gradient on a C18-column. Detection was made with a MS/MS system using positive electrospray ionisation. LOQ for PBC and IPBC in urine and blood at 0.05 mg/L. LOQ for PBC and IPBC in meat at 0.1 mg/L.	

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Matrix	limit	relevant residue	reference or comment

plant products	Not applicable
food of animal origin	Not applicable
Soil	GLC-NPD; LOQ : 0.02 mg/kg (parent compound) GLC-ECD; LOQ : 0.05 mg/kg (total; 2,4-DCBA) HPLC-UV; LOQ : 0.01 mg/kg as 1,2,4-triazole (total; 1,2,4-triazole) LC-LC-ESI/MS/MS; LOQ : 0.005 mg/kg (CGA 118 244) HPLC-LC/MS/MS; LOQ: 0.005 mg/kg as parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole)
drinking water	GLC-ECD; LOQ : 0.05 µg/l (parent compound in potable water) GC-MS : 0.05 µg/l (parent compound in potable water and surface water) *Sediment* HPLC-LC/MS/MS: 0.010 mg/kg (parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735)
surface water	GC-MS : 0.05 µg/l (parent compound in potable water and surface water)
Air	GLC-NPD; LOQ : 10 µg/m3 (parent compound) GC-MS; LOQ : 10 µg/m3 (parent compound)
body fluids / tissues	Not applicable (not toxic or very toxic substance)

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner

Methods for foodstuffs of animal origin

Reference	matrix	LOQ (mg/kg)	principle	comment	owner

Methods for soil l

Reference		LOQ (mg/kg)	principle	comment	owner

Methods for drinking water and surface water

Reference	matrix	LOQ (µg/l)	principle	comment	owner

Methods for air

Reference		LOQ (µg/m3)	principle	comment	owner

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner

Annex 4: Toxicology and metabolism –active substance

IPBC and Propiconazole

This information can be consulted in the Assessment Reports of the active substances IPBC and Propiconazole.

Annex 5: Toxicology – biocidal product

MIRECIDE-TC/94

General information

Formulation Type	8 (wood preservative)
Active substance(s) (incl. content)	IPBC and Propiconazole
Category	

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	> 2000 mg/kg
Rat LD50 dermal (OECD 402)	> 2000 mg/kg
Rat LC50 inhalation (OECD 403)	Inhalation toxicity is not required because the product is not volatile or applied in a manner that generates respirable aerosols
Skin irritation (OECD 404)	Irritating to skin
Eye irritation (OECD 405)	serious damage to eyes
Skin sensitisation (OECD 429; LLNA)	may cause sensitisation by skin contact

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	*
Toxicological data on active substance(s) (not tested with the preparation)	*
	*
Toxicological data on non-active substance(s) (not tested with the preparation)	*
	*
Further toxicological information	*IPBC has been classified in the 6th ATP of CLP regulation with H372 (larynx) Propiconazole was classifed in the 13 ATP of CLP regulation with H360D

***We do not have any additional toxicological information about biocidal product**

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Regulation 1272/2008/EC	Product classification: Category 2; Skin Irrit. 2 Eye Damage Cat.1 Skin Sens Cat.1 STOT RE 1 Hazard statements: H315: Causes skin irritation H317: May cause an allergic skin reaction H318: Causes serious eye damage H360D May damage the unborn child H372: Causes damage to organs through prolonged or repeated exposure (larynx).

Annex 6: Safety for professional operators

MIRECIDE-TC/94

Exposure assessment

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

Primary exposure of professionals

Scenario		Systemic dose [mg/kg bw/day]	
		Propiconazole	**IPBC**
Dipping, incl. handling	2 cycles	Inhalation: 2.37×10^{-4} Dermal: 2.58×10^{-3} **Total: 2.82×10^{-3}**	Inhalation: 3.5625×10^{-4} Dermal: 0.19 **Total: 0.19**
	4cycles	Inhalation: 2.375×10^{-4} Dermal: 5.16×10^{-3} **Total: 5.40×10^{-3}**	Inhalation: 3.56×10^{-4} Dermal: 0.39 **Total: 0.39**
Cleaning out dipping tank after use		Inhalation: 2.37×10^{-4} Dermal: 1.29×10^{-3} **Total: 1.53×10^{-3}**	Inhalation: 3.56×10^{-4} Dermal: 9.68×10^{-2} **Total: 9.72×10^{-2}**

Risk assessment

Scenario		AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Propiconazole						
Dipping, incl. handling	2 cycles	0.08	2.82×10^{-3}	3.53	8	2837
	4 cycles	0.08	5.40×10^{-3}	6.75	8	1481
Cleaning tank		0.3	1.53×10^{-3}	0.51	30	19623
IPBC						
Dipping, incl. handling	2 cycles	0.2	0.19	97.03	20	103
	4 cycles	**0.2**	**0.39**	**193.88**	**20**	**52**
Cleaning tank		0.35	9.72×10^{-2}	27.77	35	360

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

MIRECIDE-TC/94

General information	
Formulation Type	8 (wood preservative)
Active substance(s) (incl. content)	10.3% IPBC and 6.4% Propiconazole
Category	
Authorisation number	

IPBC and Propiconazole

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	industrial users
Secondary exposure, acute	sanding of treated wood, amateur chewing treated wood chip, infant
Secondary exposure, chronic	sanding of treated wood, professional infant playing on playground structure outdoors and mouthing adult laundering work clothes at home Adults, children and infants– inhalation of volatilised residues indoors

Conclusion:
Exposure of non-professionals and the general public to the biocidal product containing IPBC and Propiconazole as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.
Details for the exposure estimates:

Scenario	**Systemic dose [mg/kg bw/day]**	
	Propiconazole	**IPBC**
Acute: sanding of treated wood, amateur	Inhalation: 8.03×10^{-6} Dermal: 1.29×10^{-5} **Total: 2.09×10^{-5}**	Inhalation: 1.26×10^{-5} Dermal: 1.01×10^{-3} **Total: 1.02×10^{-3}**
Acute: chewing treated wood chip, infant	**Oral: 3.16×10^{-3}**	**Oral: 5.76×10^{-3}**
Chronic: sanding of treated wood, professional	Inhalation: 4.82×10^{-5} Dermal: 1.29×10^{-5} **Total: 6.11×10^{-5}**	Inhalation: 7.54×10^{-5} Dermal: 1.01×10^{-3} **Total: 1.08×10^{-3}**
Chronic: infant playing on playground structure outdoors and mouthing	Dermal : 3.68×10^{-5} Oral: 1.58×10^{-3} **Total: 1.62×10^{-3}**	Dermal: 2.88×10^{-3} Oral: 2.88×10^{-3} **Total: 5.76×10^{-3}**
Chronic, intermittent: adult laundering work clothes at home	**Dermal: 2.06×10^{-3}**	**Dermal: 0.15**
Chronic: Adults, children and infants– inhalation of volatilised residues indoors	Inhalation: Adult: 2.94×10^{-5} Child: 3.30×10^{-5} Infant: 3.39×10^{-5}	Inhalation: Adult: 1.02×10^{-3} Child: 1.14×10^{-3} Infant: 1.18×10^{-3}

Risk assessment

Scenario		AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Propiconazole						
amateur sanding		0.3	2.09×10^{-5}	0.0070	30	1434817
infant chewing wood		0.3	3.16×10^{-3}	1.05	30	9479
professional sanding		0.08	6.11×10^{-5}	0.08	8	131037
infant on playground		0.08	1.62×10^{-3}	2.02	8	4941
laundry		0.08	2.06×10^{-3}	2.58	8	3876
inhalation volatilised residues indoors	adults	0.08	2.94×10^{-5}	0.04	8	272109
	children	0.08	3.30×10^{-5}	0.04	8	242424
	infants	0.08	3.39×10^{-5}	0.04	8	235988
IPBC						
amateur sanding		0.35	1.02×10^{-3}	0.29	35	34295
infant chewing wood		0.35	5.76×10^{-3}	1.65	35	6076
professional sanding		0.2	1.08×10^{-3}	0.54	20	18460
infant on playground		0.2	5.76×10^{-3}	2.88	20	3472
laundry		0.2	0.155	77.39	20	129
inhalation volatilised residues indoors	adults	0.2	2.94×10^{-5}	0.01	20	680272
	children	0.2	3.30×10^{-5}	0.02	20	72624
	infants	0.2	3.39×10^{-5}	0.02	20	12868

Annex 8: Residue behaviour

IPBC and Propiconazole

Date: April 2012
Intended Use (critical application): wood preservative
Active substance(s): IPBC and Propiconazole
Formulation of biocidal product: water-dispersible concentrate for industrial use
Place of treatment: industrial settings

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