HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. tot toelating van de biocidenfamilie TWP 085 BPF, toelatingnummer NL-0013289-0000

Evaluation Report
Mutual Recognition

TWP 085 BPF

3rd of February 2017

BPF includes
TWP 085

Biocidal product assessment report related to product authorisation under (EU) Regulation 528/2012

Contents

1 General information about the product application

Name and address of the authorisation holder	**Name**	Troy Chemical Europe B.V.
	Address	Uiverlaan 12E 3145 XN Maassluis
Authorisation number	NL-0013289-0000	
Date of the authorisation	3rd of February 2017	
Expiry date of the authorisation	31st of March 2020	

Trade name(s)	TWP 085
Evaluating member state	DK
Name of the family in RMS	TWP 085 BPF
Active substance	3-iodo-2-propynylbutylcarbamate (IPBC) 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)
PT	8
User category	Industrial, professional and non-professional

2 Summary of the product assessment

2.1 Classification and labelling

The product will be classified as follows:

Based on Reg. (EC) 1272/2008:

The identity of all substances in the mixture that contribute to the classification of the mixture:		
-		
Pictogram:	-	Signal word: -
H-statements:	H412	Harmful to aquatic life with long lasting effects.
P-statements:	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P103	Read label before use.
	P273	Avoid release to the environment.
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	EUH208	Contains IPBC and Propiconazole: May produce an allergic reaction
Child-resistant fastening obligatory?		**no**

Tactile warning of danger obligatory?	**no**

2.2 Packaging and shelf-life

Professional

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	750ml, 1L, 2,5L, 5L, 20L, 120L, 200L, 1000L HDPE or lined steel containers	750ml, 1L, 2,5L, 5L, 20L, 120L, 200L, 1000L HDPE or lined steel containers	750ml, 1L, 2,5L, 5L, 20L, 120L, 200L, 1000L HDPE or lined steel containers

Non-professional

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	750ml, 1L, 2,5L, 5L, 20L, 120L, 200L, 1000L HDPE or lined steel containers	750ml, 1L, 2,5L, 5L HDPE or lined steel containers	750ml, 1L, 2,5L, 5L HDPE or lined steel containers

The shelf life of the product is 24 months in polymer lined metal cans and HDPE

2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties, analytical methods and risk assessment regarding physical and chemical properties we refer to the Product Assessment Report of the original authorisation.

2.4 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to the Product Assessment Report of the original authorization (TWP 085 BPF – updated version January 2013) by the RMS Denmark. The conclusions of the RMS are acceptable.

2.4.1 Instructions for the use(s)

The applicant has provided a Dutch SPC. This has been adapted to our standards.

2.5 Risk assessment for human health

For the risk assessment for human health we refer to the Product Assessment Report of the original authorisation.

The formulation TWP 085 BPF contains 0.75% IPBC and 0.24% propiconazole. It is used as wood preservative (PT08) for industrial, professional and amateur use. The modes of application include in-situ brushing, rolling and spraying (professional and amateur) as well as industrial dipping, flow-coating, automated spraying and vacuum pressure. The Product Assessment Report (PAR) was prepared by the eCA Denmark (DK).

The intended use is covered by the CAR for IPBC and propiconazole.

No studies were submitted with the formulation. Based on the calculation rules no classification is warranted for acute toxicity, for skin or eye irritation or for sensitising properties. However, based on the sensitizing properties of both active substances the following sentence shall be stated on the label: Contains IPBC and Propiconazole: May produce an allergic reaction. The conclusions of DK on formulation toxicity are accepted by the Ctgb.

Dermal absorption studies for the active substances are available in the EU dossiers. The solvent based formulation containing 0.6% IPBC is considered a representative worst-case for the water-based ready-to-use product TWP 085 BPF containing 0.75% IPBC. Therefore, the IPBC dermal absorption value of 30% has been used in the human exposure assessment of TWP 085 BPF. For propiconazole, data (reviewed in the CAR) based on tested concentrations of 0.06% and 0.006%
(solvent based product) gave dermal penetration values of 2.4% and 1.6%, respectively. The value of 2.4% has been used for the representative products in the CAR containing 1% (water-based) and 1.4% (solvent based) propiconazole. Therefore, DK used the dermal absorption value of 2.4% for propiconazole in the human exposure assessment of TWP 085 BPF. This is accepted by the Ctgb.

For industrial users, DK considered the 'Timber pre-treatment (water)" scenario from BEAT to estimate the exposure from the use of TWP085 BPF for automated dipping /vacuum pressure /automated spraying/flow-coating. Although BEAT is not commonly used, the conclusions were the same as when the exposure was calculated with Handling model 1 (4 cycles). The exposure resulted in 90% of the AEL for IBPC and 6.1% for propiconazole, with the use of protective gloves and coated coveralls.

Professionals apply TWP 085 BPF by brushing and spraying. Exposure for brushing was estimated with Consumer painting model 3 leading to 18% of the AEL for IPBC and 1.5% for propiconazole. For this risk assessment DK considered a 25% reduction factor for normal clothing, and assumed the wearing of gloves as part of daily routine for professional workers. According to the HEEG opinion 9 on default protection factors for protective clothing and gloves, the value of 25% may be considered for dry cotton coveralls only for dry substances. This is not the case for TWP 085 BPF. Moreover, the first tier of the risk assessment needs to be performed without gloves. When this reduction of 25% and the use of gloves are not taken into account, a safe use for the unprotected users can still be concluded (82% of the AEL for IPBC and 9% for propiconazole).
For spraying, DK considered the 'Remedial biocides" scenario from BEAT to estimate the exposure from the use of TWP085 BPF for spraying. The exposure resulted in 98% of the AEL for IBPC and 22.5% for propiconazole, with the use of protective gloves and impermeable coveralls (95% reduction). Although BEAT is not commonly used, the approach by DK was worst case. The exposure resulted in 59.2% of the AEL for IBPC and 2.8% for propiconazole when the exposure was calculated with Spraying model 2 (for powered spray application at 4 to 7 bar pressure according to Head hoc recommendation no 6) with the use of gloves and coveralls (90% reduction). From this the Ctgb concludes that the use of gloves and coveralls will provide sufficient reduction.

Brushing and spraying for non-professionals is estimated with Consexpo. DK assumed that non-professionals wear trousers, boots and long-sleeved shirts for which a penetration of 50% is considered. According to the HEEG opinion 9 on default protection factors for protective clothing and gloves, the value of 50% may be considered for dry substances or a liquid formulation where contamination is judged to be relatively light (e.g. from using an aerosol canister or application by a trigger spray). The applicability of such measure as risk mitigation is again debated in HEADhoc recommendation no. 8, as no warranty is given that consumers will wear such clothes. Even without the use of the protection factor of 50%, a safe use for the unprotected non-professional user can be concluded:
brushing: 53% of the $AEL_{short\text{-}term}$ for IPBC and 1.5% of the $AEL_{short\text{-}term}$ for propiconazole

spraying: 16% of the AEL $_{short\text{-}term}$ for IPBC and 0.6% of the AEL $_{short\text{-}term}$ for propiconazole

The general public (adult, child and infant) can be secondarily exposed to TWP 085 BPF via the oral, dermal and inhalation routes. The following scenario's were assessed by DK by models/approaches as described by the TNsG and/or HEEG guidances:
Acute secondary exposure:
– Adult : Inhalation of wood dust during sanding treated wood (acute)
– Infant : Chewing piece of wood
– Child and infant: Touching freshly treated surface
Chronic secondary exposure:
– Adult : Inhalation of wood dust during sanding treated wood (chronic)
– Child and infant: Playing on timber structures (playground)
– Adult, child and infant: Inhalation of volatilised residues, indoors
From this it was concluded that there is no unacceptable health risk from secondary exposure.

The conclusions from the risk assessments for industrial, professional and non-professional users as well as the secondary exposure are accepted by the Ctgb.

Furthermore, DK did not identify any substance of concern.

TWP 085 BPF contains two active substances, namely IPBC and propiconazole. The RMS DK has not performed the assessment of combined exposure to both substances.

However, the guidance on the evaluation of combined toxicity proposed by France has already been endorsed at the TM IV 2012 and included in the current ECHA guidance. Therefore the risk assessment for combined toxicity was performed by the Ctgb.

As a first tier, the adverse toxicological effects of both compounds are considered to be additive by default. Therefore, if the sum of risk indices per exposure scenario for both substance is < 1, no risk of adverse toxicological effects from combined exposure is expected. If a sum of the risk indices exceeds 1, as a second tier approach, a more detailed assessment is necessary, including the analysis of the mode of action and target organs for each substance. If the substances have different modes of action and different target organs are affected, the additivity approach is not applicable and the effects of each substance should be regarded separately. In that case no concern for combined toxicological effects of the substances exists.

The sum of the risk indices exceeds 1(100%) for the application by spraying by professionals: 98% for IPBC + 22.5% for propiconazole. Therefore, as a second tier, toxicological profiles of each substance will be assessed. This is based on an AEL 0.2 mg/kg bw/d for IPBC (based on non-specific effects (reduced body weights and body weight gains) and histopathological changes in stomach, forestomach and salivary glands), and an AEL of 0.08 mg/kg bw/d for propocinazole (based on liver effects).

For propiconazole, the most critical effect is liver toxicity. Increased liver weights and slight histopathological changes in the liver were seen already in short-term studies Propiconazole is a strong inducer of xenobiotic metabolism and tumour promoter in rodents. Other effects observed are a slight increase in the incidence of cleft palate was observed; and slight reproductive effects (reduced litter sizes and pup weights, reduction in testes/epididymides weights). The systemic AEL of 0.08 mg/kg bw/day was based on the liver toxicity in parental animals in the 2-generation study with rats. The short-term systemic AEL of 0.3 mg/kg bw/day was based on the developmental changes (slight increases in cleft palate, increased visceral and skeletal variations) in a teratology study with rats.

For IPBC, the observed changes in the repeated dose oral toxicity studies included local effects in the stomach, liver , kidneys and thyroids. In the repeated dose inhalation toxicity studies decreased RBC cholinesterase activity in females and decreased brain cholinesterase activity in both sexes were observed, in addition to local effects in the larynx. IPBC did not affect fertility and did not cause developmental toxicity. The long-term systemic AEL of 0.2 mg/kg bw/day was based on non-specific effects (reduced body weights and body weight gains) and histopathological changes in stomach, forestomach and salivary glands in the chronic toxicity study with rats. The short-term systemic AEL of 0.35 mg/kg bw/day was based on the non-specific effects (reduced body weight and body weight gain) and increased absolute and relative kidney and liver weights in the 90-day study with rats.

As can be seen from these data, both substances cause liver toxicity. For IPBC, liver weights were increased at the interim kill in a chronic toxicity rat study at 40 mg/kg bw/day and 80 mg/kg bw/day, but this effect was not noted at the terminal kill. In two available 90-day toxicity studies with rats, increased absolute and relative liver weights were also observed from 30 to 40 mg/kg bw/day. In the 90-day study with rabbits, increased liver weights were observed at high dose levels (75 and 150 mg/kg bw/day).
In summary, liver effects were observed in the repeated dose toxicity studies with both substances. hence, specific liver AEL should be derived for the refinement of the combination toxicology assessment. For IPBC an AEL medium-term of 0.3 mg/kg bw/day for liver effects could be derived based on NOAEL of 30- 40 mg/kg bw/day for increased liver weights in a 90d toxicity rat and at the interim kill in the chronic rats studies. The AEL of 0.08 mg/kg bw/d for propiconazole was already based on liver effects.

The resulting risk index for liver effects due to combined exposure during spraying will be 65.4%(IPBC) + 22.5%(propiconazole) =87.8%. Therefore it is assumed that no adverse effects are expected from concomitant exposure to IPBC and propiconazole due to combined toxicity.

2.6 Risk assessment for the environment

Summary of the PAR
TWP 085 BPF is a wood preservative (PT08) intended for use classes 2 and 3. The product contains IPBC (7.5 g/L) and propiconazole (2.4 g/L) and is ready to use. According to the RMS no substances of concern other than the active substances are present in the product. The product is applied non-professionally by brushing, rolling, or spraying, professionally the product is applied by dipping, flow-coating, brushing, rolling, spraying, and (only for industrial use) vacuum pressure. The dose is 39.2-47.0 kg product/m^3 for vacuum pressure and 182-222 g product/m^2 for surface treatment.

The RMS (DK) has assessed the following emission routes:

- industrial application and storage (dipping, automated spraying, and vacuum pressure);
- in-situ application (brushing/rolling and spraying);
- service life (bridge over pond, timber classed house, and noise barrier).

Emission for wood in service was calculated over 5 years (surface treatment), 15 years (automated spraying and dipping), and 20 years (vacuum pressure). Leaching rates for the concerning product from a field leaching study are available for both surface treatment and vacuum pressure. Leaching rates were determined without and with a topcoat. However, only the leaching rates without topcoat were applied for all IPBC-applications and for propiconazole applied by vacuum pressure (TIME2). The leaching rates were corrected for the advised maximum dosages (47 kg/m^3 or 222 g/m^2). PECs were calculated from the parameters as included in the CAR. No new studies were submitted.

The RMS concluded that TWP 085 BPF can be applied safely provided that residual fluids and spills are collected for reuse or disposal and wood is stored on impermeable hard standings or under shelter.

Propiconazole is considered as persistent, but not bioaccumulative and/or toxic. None of the PBT-criteria are fulfilled for IPBC and its metabolites. Both actives have no endocrine properties. Therefore, none of the active substances fulfils the criteria for exclusion or comparative assessment.

NL's conclusions:
NL has the following comments on the PAR:

- initial concentrations for in-situ applications (spraying and brushing) due to spillages were not calculated;
- the proposed risk mitigation regarding storage on impermeable hard standings was not substantiated by an additional risk assessment for the sewage treatment plant;
- the product is classified as H412, but this was not noted in the PAR. The applicant already included H412 on their SPC, label, and SDS.

Although the risk assessment is considered incomplete, NL is able to authorise TWP 085 BPF. Based on their experiences with other preservatives based on IPBC and propiconazole for PT07-09, application of TWP 085 BPF as a wood preservative will not result in unacceptable risks for the environment provided that:

1. residues and spills during industrial treatment must be collected and reused or disposed as hazardous waste;
2. emission to adjacent soils during application by brushing , rolling, or spraying must be prevented by sufficient coverage. The applicant already restricted application above or adjacent of surface water.

Risk mitigation 2 is not yet included on the SPC. Emission from industrial storage on impermeable hard standings to STP and the subsequent aquatic and terrestrial environment was not assessed in the PAR. However, an additional risk assessment by NL demonstrated that ∑PEC:PNEC << 1 (sum propiconazole and PBC). Therefore, adjusting the proposed RMM is not necessary.

For the risk assessment for the environment we refer to the Product Assessment Report of the original authorisation.

Overall conclusion for the aspect environment: The conclusions in the risk assessment of the RMS are valid.

2.7 Measures to protect man, animals and the environment

For the measures to protect animals and the environment we refer to the Product Assessment Report of the original authorisation and the SPC of the CMS NL.

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves, suitable protective clothing) professional and the unprotected non-professional user after dermal and respiratory exposure to IPBC and propiconazole as a result of the application of TWP 085 BPF, when used in accordance to the SPC.

Furthermore, when used according to the SPC, no adverse health effects are expected for the general public by indirect exposure to IPBC and propiconazole as a result of the application of TWP 085 BPF.

2.8 Substitution/exclusion criteria and comparative assessment

TWP 085 BPF does not contain any active substances that are considered candidate for substitution.

3 Proposal for decision

The authorisation of TWP 085 BPF is based on mutual recognition of the authorisation of RMS DK. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is concluded that the application of TWP 085 BPF according to the use instructions as stated in the SPC, will be effective and that there will be no harm for the health of humans and for the environment.