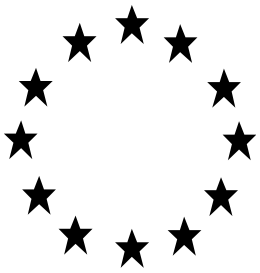
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the competent authority)



RESISTOL 6220

Product type 8

3-iodo-2-propynylbutylcarbamate (IPBC), penflufen and permethrin

Case Number in R4BP: BC-GS072244-26

Competent Authority: FRANCE

Date: January 2024

1 Table of Contents

Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	FR-CA	BC-GS072244-26	19.01.2024	Initial assessment	

1 Conclusion

RESISTOL 6220 is an SL biocidal product containing IPBC, Penflufen and Permethrin as active substances. The product is used as a product type 8 by industrial users for the control of House longhorn beetle, Brown rot fungi and Subterranean termites.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the preventative treatment for wood on use classes 1 and 2 by industrial users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product contains a non-active substance (so called "co-formulant") which is considered as a substance of concern (for human health and environment). The non-active substance considered as a substance of concern is 2-phenoxyethanol. Two other co-formulants, Diethylene glycol monophenyl ether and Ethoxylated isotridecanol, are identified as SoC for human health only. More detailed information on the substance(s) of concern is provided in the confidential annex.

The biocidal product should be considered not to have endocrine-disrupting properties.

Based on the available information, none of the co-formulants contained in the family are regulatory identified as endocrine disruptors or have significant ED properties.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains permethrin which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: persistent (P) and toxic (T).

No comparative assessment was performed as according to the document CA-June22-Doc.4.2, a comparative assessment in accordance with Article 23 should only be carried out when an active substance is identified as meeting the substitution criteria in the renewal of approval Regulation with regards to Article 10 (5) of the BPR and when this status is validated by ECHA's Biocidal Product Committee (BPC).

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer(s) of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance(s) in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer(s) of the active substances are listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

The final report of the stability study at ambient temperature in the commercial packaging is required in post-authorisation.

Note for labelling: Do not store above 40°C.

Pour gently during the dilution of the product.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances and residues are available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Validated analytical methods are provided for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against wood boring beetles (*H. bajulus*), termites (*Reticulitermes spp*.) and wood destroying fungi (brown rot) for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since 2-phenoxyethanol has been identified as a substance of concern, the human health risk assessment is based on penflufen, permethrin, IPBC and on 2-phenoxyethanol.

Based on the risk assessment performed (qualitative and quantitative risk assessment), no unacceptable risk has been demonstrated for industrials considering PPE and RMMs as specified in the SPC.

Dietary risk assessment

The intended use description of the product RESISTOL 6220 indicates that this use is not relevant in terms of residues in food and feed. However, to prevent any food or feed contamination, the following risk mitigation measure is added:

- Do not use on wood which may come in direct contact with food feeding stuff and livestock animals;
- The person responsible for placing the treated wood on the market must ensure that the treated wood is not intended for uses involving contact with food, feed or livestock.

Risk assessment for animal health

A risk assessment for animal health is expected. The risk assessment for the intended uses applied by the applicant is considered as covered by the secondary exposure of general public, especially infant and toddler. More information is available in section 3.7 of the PAR.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for companion animals, if the directions for use, as specified in the SPC, are followed.

Risk assessment for the environment

A qualitative risk assessment for the environment has been carried out for all the intended uses as applied by the applicant.

Since 2-Phenoxyethanol (CAS#122-99-6) been identified as substance of concern, the qualitative risk assessment for the environment is based on all actives substances and on 2-Phenoxyethanol.

Based on negligible exposure foreseen for the industrial uses on wood in classes 1 and 2 only, it is unlikely that the intended uses cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

In order to prevent any releases during the industrial application phase, the following risk mitigation measures are proposed:

- Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.
- All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
- Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal'.
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

Post-authorisation conditions

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

Description	Due date
Final results of stability study at ambient temperature in the commercial packaging	2 years after the authorisation of the product

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	PT8
Type(s) of formulation	SL – soluble concentrate

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
[1]	Industrial Preventative Treatment	PT8	Brown rot fungi Wood boring beetles: House longhorn beetle (*Hylotrupes bajulus*) - Larvae Termites (Reticulitermes spp.	**Dipping-** Preventative treatment of wood and constructional timbers in Use Classes 1 & 2. **Deluge/Enclosed Spray** - Preventative treatment of wood and constructional timbers in Use Classes 1 & 2. The product can be applied to both softwood and hardwood	**Dipping**: Dilute to 6.46-12.92% with water and apply by automated dipping system at the following retentions: 6.46 g/m^2 **Deluge/ Enclosed Spray:** Dilute to 6.46-12.92% with water and apply by enclosed spray/ deluge system at the following retentions: 6.46 g/m^2	Professional	R	-

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

2.3 Identity and composition

The identity and composition of the biocidal product are

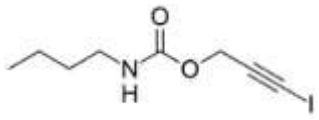
identical ☐
not identical ☒

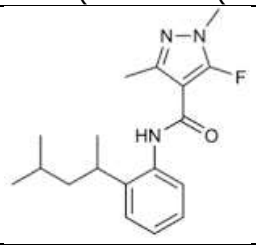
to the identity and composition of the product(s) evaluated in connection with the [approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

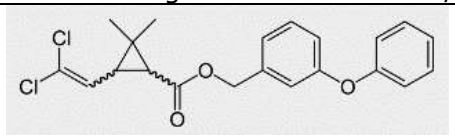
2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	IPBC
Chemical name	3-iodo-2-propynyl butylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	98%
Structural formula	

Main constituent(s)	
Common name	Penflufen
Chemical Name	5-Fluoro-1,3-dimethyl-N-{2-[(2RS)-4-methylpentan-2-yl]phenyl}-1H-pyrazole-4-carboxamide
EC number	619-823-7
CAS number	494793-67-8
Index number in Annex VI of CLP	N/A
Minimum purity / content	98% (1:1 ratio (R:S) ratio of enantiomers)
Structural formula	

Main constituent(s)	
Common name	Permethrin
Chemical Name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)- 2,2-dimethylcyclopropanecarboxylate

EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	93% w/w sum of all permethrin isomers. Total cis range: 25 – 28% ratio Total trans range: 72-75% ratio 1Rcis range: 7.9 – 8.3% w/w 1Scis range: 15.8 – 16.7% w/w 1Rtrans range: 45.4 – 46.1% w/w 1Strans range: 22.5 – 23.0 % w/w
Structural formula	

2.5 Information on the source(s) of the active substance(s)

Is the source of IPBC the same as the one(s) evaluated in connection with the [approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012 / inclusion of the active substance(s) in category 6 of Annex I of Regulation No. 528/2012]?

☒ Yes

☐ No

Moreover, a technical application is used and approved (TAPP identification: BC-ME049519-34).

Is the source of permethrin the same as the one(s) evaluated in connection with the [approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012 / inclusion of the active substance(s) in category 6 of Annex I of Regulation No. 528/2012]?

☒ Yes

☐ No

Is the source of penflufen the same as the one(s) evaluated in connection with the [approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012 / inclusion of the active substance(s) in category 6 of Annex I of Regulation No. 528/2012]?

☒ Yes

☐ No

2.6 Candidate(s) for substitution

The biocidal product contains permethrin which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: persistent (P) and toxic (T).

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product contains the active substances "Penflufen", "Permethrin" and "IPBC" which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, none of the co-formulants contained in the family are regulatory identified as endocrine disruptors or have significant ED properties.

Please refer to the Confidential Annex and the embedded Excel file for further details.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	**Labelling**
Hazard Class and Category code	Skin Sens. 1 Eye Dam.1 Aquatic acute Cat 1 Aquatic chronic Cat 1	Skin Sens. 1 Eye Dam.1 Aquatic chronic Cat 1
Hazard Pictograms	[GHS05] [GHS09]	[GHS05] [GHS09]
Signal word(s)	[Danger]	[Danger]
Hazard statements	H317: May cause an allergic reaction H318: Causes serious eye damage H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects	H317: May cause an allergic reaction H318: Causes serious eye damage H410: Very toxic to aquatic life with long lasting effects
Precautionary statements *	P261: Avoid breathing dust/vapours P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of water. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage P501: Dispose of contents/container according to local regulation	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements		
Notes	-	

2.9 Letter of access

Letters of Access for IPBC, penflufen and permethrin have been submitted.

2.10 Data submitted in relation to product authorisation

No new data on the active substance or substances of concern have been submitted.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
IBC	- 1000 Litres - 640 Litres	HDPE	Screw cap HDPE	Industrial	Yes

3.2 Physical, chemical, and technical properties

Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation.

The product does not contain hydrocarbons nor H304 co-formulant content ≥10% and therefore is not classified for aspiration hazard.
Packaging: IBC HDPE
Concentration of uses: 6.46 - 12.92% by spraying and dipping

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR Comment
3.1.	Appearance at 20 °C and 101.3 kPa					
3.1.1.	Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	liquid	IUCLID 3.1 [redacted]	Acceptable
3.1.2.	Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	Slightly yellow	IUCLID 3.1 [redacted]	Acceptable
3.1.3.	Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	Pungent	IUCLID 3.1 [redacted]	Acceptable
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	pH (1 % dilution): 5.61 pH (neat): 6.54	IUCLID 3.2 [redacted]	Acceptable
3.3.	Relative density / bulk density	OECD 109 resp. EU A.3	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532%	1.0283 g/cm^3	IUCLID 3.3 [redacted]	Acceptable

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th><th>FR Comment</th></tr>
<tr><td></td><td></td><td></td><td>permethrin, 0.650% IPBC</td><td></td><td></td><td></td></tr>
<tr><td>3.4.1.1.</td><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3

OPPTS 830-6302, -6304

CIPAC MT 75

CIPAC MT 41

HPLC method validated (report VB21041204 G926)</td><td>Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC</td><td>
<table>
<tr><th>Parameter</th><th colspan="2">Time (weeks) at 40°C in 0.75L HDPE</th></tr>
<tr><td></td><td>0</td><td>8</td></tr>
<tr><td>Physical state</td><td>Liquid</td><td>Liquid</td></tr>
<tr><td>Odour</td><td>Pungent</td><td>Pungent</td></tr>
<tr><td>Colour</td><td>Slightly yellow</td><td>Between RAL 1014 Ivory and RAL 1015 Light Ivory</td></tr>
<tr><td>pH (1%)</td><td>5.61</td><td>5.49</td></tr>
<tr><td>pH (neat)</td><td>6.54</td><td>6.38</td></tr>
<tr><td>Dilution stability (12.92%w/v in water)</td><td colspan="2">The solution was clear and homogeneous with a little foam on the surface after 30 minutes.
No separated material was observed. After 24 h no further changes were observed.</td></tr>
<tr><td>Penflufen content</td><td>0.278%</td><td>0.287%</td></tr>
<tr><td>Permethrin content</td><td>1.640% (cis:trans ratio 0.333)</td><td>1.694% (cis:trans ratio 0.333)</td></tr>
<tr><td>IPBC content</td><td>0.652%</td><td>0.657%</td></tr>
</table>
750 ml test item was stored in a HDPE container for 8 weeks at 40 °C. No changes or deterioration of the packaging was observed following storage.</td><td>IUCLID 3.4.1
[redacted]</td><td>Acceptable
The product is stable after 8 weeks at 40°C.
Restriction measure: Do not store above 40°C</td></tr>
</table>

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th><th>FR Comment</th></tr>
<tr><td>3.4.1.2.</td><td>Storage stability test – long-term storage at ambient temperature</td><td></td><td></td><td>Study began 17th August 2021
Storage has been done in the sponsor’s commercial container

<table>
<tr><th>Parameter</th><th colspan="2">Time (months) at 20°C in 750 mL HDPE</th></tr>
<tr><th></th><th>0</th><th>12</th></tr>
<tr><td>Physical state</td><td>Slightly viscous clear liquid</td><td>Slightly viscous clear liquid</td></tr>
<tr><td>Odour</td><td>Pungent</td><td>Pungent</td></tr>
<tr><td>Colour</td><td>Slightly yellow</td><td>Slightly yellow</td></tr>
<tr><td>pH (1%)</td><td>5.61</td><td>5.54</td></tr>
<tr><td>pH (neat)</td><td>6.54</td><td>6.43</td></tr>
<tr><td>Dilution stability (12.92%w/v in water)</td><td colspan="2">The solution was clear and homogeneous with a little foam on the surface.
No separated material was observed.</td></tr>
<tr><td>Penflufen content</td><td>0.278%</td><td>0.295%</td></tr>
<tr><td>Permethrin content</td><td>1.640% (cis:trans ratio 0.333)</td><td>1.643% (cis:trans ratio 0.334)</td></tr>
<tr><td>IPBC content</td><td>0.652%</td><td>0.626%</td></tr>
<tr><td>Packaging aspect</td><td>No damage, no leakage, no peculiarities</td><td>No damage, no leakage, no peculiarities</td></tr>
<tr><td>Packaging weight</td><td>637.8 g</td><td>637.7 g</td></tr>
</table>
</td><td>IUCLID 3.4.1
[redacted]</td><td>Interim results confirm that the product is stable up to 12 months when stored at ambient temperature in its commercial container.

Final results are required in post-authorisation.</td></tr>
</table>

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR Comment
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	No additional phases or separated material were observed after the storage of the test item for 7 days at 0.0 ± 0.9 °C.	IUCLID 3.4.1 [redacted]	Acceptable Product is stable at low temperature
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Waiver		Products are in opaque packaging, therefore light is not expected to have any detrimental effect on the products.		Acceptable No other data is required as packaging are opaque.
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	Accelerated storage stability tests indicate that detrimental effects are not expected as a result of temperature or humidity.	IUCLID 3.4.1 [redacted]	Acceptable (see accelerated storage) The formulation is a water based product and packaging are waterproof.
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	See accelerated storage results.	IUCLID 3.4.1 [redacted]	Acceptable (see accelerated storage)
3.5.1.	Wettability			Resistol 6220 is a water based concentrate. Thus, testing of wettability is not applicable.		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR Comment
3.5.2.	Suspensibility, spontaneity, and dispersion stability			Resistol 6220 is a water based concentrate. Thus, testing of suspensibility, spontaneity, and dispersion stability are not applicable		
3.5.3.	Wet sieve analysis and dry sieve test			Resistol 6220 is a water based concentrate. Thus Wet sieve analysis and dry sieve test are not applicable		
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability			Resistol 6220 is a water based concentrate. Thus Emulsifiability, re-emulsifiability and emulsion stability are not applicable		
3.5.5.	Disintegration time			Resistol 6220 is a water based concentrate. Thus, testing of wettability is not applicable		
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability			Resistol 6220 is a water based concentrate. Thus, testing of Particle size distribution, content of dust/fines, attrition, friability is not applicable		
3.5.7.	Persistent foaming	CIPAC MT 47	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	Measurement Sample One (2.15%): Initial : 99mL After 1min: 94mL After 12min: 13mL Measurement Sample Two (12.9%): Initial : 125 mL After 1min: 118 mL After 12min: 12 mL	IUCLID 3.5 [redacted]	The product is highly foaming, nevertheless, the foam decreases between 1 and 12 min. A note on the label is added: "***Pour gently during the dilution of the product***"
3.5.8.	Flowability/pourability/dustability			Resistol 6220 is a water based concentrate. Thus, testing of Flowability/pourability/dustability is not applicable		
3.5.9.	Burning rate — smoke generators			Resistol 6220 is a water based concentrate. Thus, testing for burning rate is not applicable		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR Comment
3.5.10.	Burning completeness — smoke generators			Resistol 6220 is a water based concentrate. Thus, testing for burning completeness is not applicable		
3.5.11.	Composition of smoke — smoke generators			Resistol 6220 is not a smoke generator. Thus, testing for composition of smoke is not applicable		
3.5.12.	Spraying pattern — aerosols / spray			Resistol 6220 is a water based concentrate, thus testing for spraying pattern is not applicable		
3.6.1.	Physical compatibility	Waiver	-	No claims of compatibility are made on the label.		
3.6.2.	Chemical compatibility	Waiver	-	No claims of compatibility are made on the label.		
3.7.	Degree of dissolution and dilution stability	CIPAC MT 41	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	A 12.92 % w/v solution in CIPAC D water was tested. The solution was clear and homogeneous with a little foam on the surface. No separated material observed.	IUCLID 3.4.1 [redacted]	Acceptable at the highest concentration of use.
3.8.	Surface tension	OECD 115 EU A.5	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	33.52 ± 0.09 mN/m at 20.1 °C (at 12.92% w/v). Product can be classified as surface active.	IUCLID 3.8 [redacted]	Acceptable
3.9.	Viscosity	OECD 114 / DIN 53015	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	16.683 ± 0.001 mPa * s at 20.00 ± 0.06 °C and 12.438 ± 0.037 mPa * s at 40.0 ± 0.1 °C	IUCLID 3.9 [redacted]	Acceptable

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
RESISTOL 6220 is a *soluble concentrate*. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is as slightly yellow liquid, with pungent odour. In 1% aqueous solution, it has a pH value of 5.6 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. Final results of the long term stability study is required in post-authorization. Its technical characteristics are acceptable for an SL formulation **Implications for labelling:** Do not store above 40°C. Pour gently during the dilution of the product. Shelf life: 2 years

3.3 Physical hazards and respective characteristics

Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation. All required tests should be performed according to CLP Regulation. If data is waived, it should be clearly explained why the biocidal product is not classified. Note that waivers should be based on information in line with the CLP requirements.

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR comments
4.1.	Explosives	[i] ECHA Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0, July 2017. [ii] United Nations recommendations on the Transport of Dangers good, Model Regulations, Manual of Tests and Criteria, 7th Ed., 2019.	Resistol 6220 Resistol 6220 Batch n° 1742	None of the components of Resistol 6220 are considered to be explosive. The product as a whole would not be expected to behave differently with regards to explosivity compared with individual constituents when combined. It is therefore concluded that the product is not likely to undergo rapid decomposition with the evolution of gases or release of heat and so does not present a risk of explosion and therefore should not be classified under this CLP hazard class. In addition, a DSC screening test from 20 to 500 °C showed no exothermic decomposition.	IUCLID 4.1 [redacted]	Acceptable Product is not explosive according to CLP regulation
4.2.	Flammable			Not applicable Resistol 6220 is a water based		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR comments
	gases			product		
4.3.	Flammable aerosols			Not applicable Resistol 6220 is a water based product		
4.4.	Oxidising gases			Not applicable Resistol 6220 is a water based product		
4.5.	Gases under pressure			Not applicable Resistol 6220 is a water based product		
4.6.	Flammable liquids	EU Method A.9 (Flash-Point) (closed cup)	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	Heating was performed up to boiling point at 100.8 °C and 100.6 °C during the first and the second pretest, respectively. In the pre-tests, no flash point was detected up to the boiling point. Therefore, no flash point can be stated for Resistol 6220.	IUCLID 4.6 [redacted]	Acceptable Product is not flammable according to CLP regulation.
4.7.	Flammable solids			Not applicable Resistol 6220 is a water based product		
4.8.	Self-reactive substances and mixtures		Resistol 6220 Batch n° 1742	a DSC screening was conducted from 20 to 500 °C and no exothermic reaction was observed.		Acceptable, the product is not a candidate for classification as UN Class 4, Division 4.1
4.9.	Pyrophoric liquids			Due to water content and known experience, Resistol 6220 does not have pyrophoric properties		Acceptable
4.10.	Pyrophoric solids			Not applicable Resistol 6220 is a water based product		
4.11.	Self-heating substances and mixtures			Due to water content, Resistol 6220 is not self heating.		Not relevant, the product

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR comments
						is liquid.
4.12.	Substances and mixtures which in contact with water emit flammable gases			Not applicable, Resistol 6220 is water based.		
4.13.	Oxidising liquids	ECHA Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0, July 2017. [ii] United Nations recommendations on the Transport of Dangers good, Model Regulations, Manual of Tests and Criteria, 7th Ed., 2019.	Resistol 6220	The chemical structures and classifications of the individual components of the product were evaluated for an indication of the presence of oxidising properties. The components do contain oxygen, but the oxygen atoms present are chemically bonded only to carbon or hydrogen. It is therefore concluded that Resistol 6220 is incapable of reacting exothermically with combustible materials and should not be classified as oxidising under CLP or GHS.	IUCLID 4.13 [redacted]	Acceptable Product is not oxidising according to CLP regulation.
4.14.	Oxidising solids			Not applicable Resistol 6220 is a water based liquid.		
4.15.	Organic peroxides			Not applicable no organic peroxides are in Resistol 6220		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR comments
4.16.	Corrosive to metals	Test C.1, Section 37.4, Manual of tests and criteria (71h ed., 2019)	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	Metal plates, aluminium (7075-T6) and steel (1.0037), each 50*20*2 mm were tested at 55°C for 7 days. Neither mass loss nor reduction of uniform thickness exceeding the criteria for uniform or localised corrosion attack was observed after 7 days at 55°C Less than 13.5% of loss of weight on steel (max. -0.2% weight) and aluminium (max. -0.0% weight) were obtained. No localized corrosion was observed (max 0 µm). The test item Resistol 6220 is therefore not classified as corrosive to metals according to the criteria set out in the test method.	IUCLID 4.16 [redacted]	Acceptable Product is not corrosive to metal according to CLP regulation.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	EU A.15	Resistol 6220, batch JM2-106, 0.283% penflufen, 1.532% permethrin, 0.650% IPBC	The lowest value of the auto ignition temperature was 450 °C. This value was determined using 9 drops test item. The test item showed auto ignition after 118 seconds. The auto ignition temperature (result of determination) is the lowest value of the lowest values of the three experiments, rounded down to a whole multiple of 5 °C. Therefore, the auto ignition temperature was stated as 450 °C.	IUCLID 4.17.1 [redacted]	Acceptable
4.17.2.	Relative self-ignition temperature for solids			Not applicable Resistol 6220 is a water based liquid		
4.17.3.	Dust explosion hazard			Not applicable Resistol 6220 is a water based liquid		

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

Refer to the Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C) when compiling this section. The guidance is available on the ECHA website at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation. Describe the analytical methods used for the analysis of the active substance(s), residues, relevant impurit(y/ies) and substance(s) of concern in the biocidal product.

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

	Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
	Principle of the method *[HPLC-UV]:* A HPLC-UV method for the determination of penflufen, permethrin and IPBC in the biocidal product Resistol 6220 was validated. The test item was separated with a Hypersil BDS C18 5 µm, 250*4.6 mm with guard column and detected with HPLC-UV (235nm).											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**HorRat**	**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	N	Range	Mean	RSD	Concentration tested	Number of replicates			
IPBC	*10 -70 mg/L, 6 samples.* Linear function, Y = 0.08129x -0.1.7104 R^2 = 0.99842	no interfering signals are present in the retention time range of the active	Around 0.65% (31.5mg/L)	6		100.3	1.2	0.662% Hr<1	10	0.44		IUCLID 5 [redacted]

		substance signal or < 3% of the proposed LOQ										
Penflufen	5-50 mg/L, 6 samples. Linear function, Y = 0.63146 x + 0.1274 R^2 = 0.99987	No interfering signals are present in the retention time range of the active substance signal or < 3% of the proposed LOQ	Around 0.284% (14.9 mg/L)	6		100.4	0.8	0.284% Hr<1	10	0.16		IUCLID 5 [redacted]
Permethrin	25-150 mg/L, 6 samples. Linear function, Y = 0.79663 x + 0.41118 R^2 = 0.99992	No interfering signals are present in the retention time range of the active substance signal or < 3% of the proposed LOQ	Around 1.615%(73.9 mg/L)	6		100.1	1.1	1.615% Hr<1	10	0.22		IUCLID 5 [redacted]

Analytical methods for the analysis of the product for chirality of permethrin											
Principle of the method *[HPLC-MS]:* An analytical method for the determination of permethrin content in Resistol 6220 was validated following the test guidelines SANCO/3030/99 rev.4 11/07/00 and Regulation (EU) No 528/2012, of the European Parliament and of the Council (Biocidal Products Regulation, the BPR). The study was designed to determine the composition of individual permethrin isomers - 1S Cis (S,S), 1R Cis (R,R), 1S Trans (S,R) and 1R Trans (R,S) using high performance liquid chromatography (HPLC, column Zebron ZB-5, 15 m, 0.25 mm ID, 0.25µ film thickness) with mass spectrometry detection (MS).										
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	N	Range	Mean	RSD	Concentration tested	Number of replicates		
1S Cis (S,S)	*Method was not linear* the quadratic function (y = ax2+bx+c) was selected to describe the detector response as a function of the isomer concentration. The correlation coefficient (R) of polynomial curve fit for the standard calibrations was greater than 0.99 over the standard calibration range.	No interfering signals are present in the retention time range of the active substance signal or < 3% of the proposed LOQ	80 , 100, 120% of nominal (2.84, 3.41 and 4.19 µg/mL respectively)	3 for each level	At 80% nominal At 100% nominal At 120% nominal	103.9 99.7 102.1		0.265% w/w Hr<1	5		[redacted], 2021, [redacted]
1R Cis (R,R)	*Method was not linear* the quadratic function (y = ax2+bx+c) was selected to describe the	No interfering signals are present in the retention time range	80 , 100, 120% of nominal (1.62, 1.97 and 2.40 µg/mL	3 for each level	At 80% nominal At 100%	104.5 101.7		0.124% w/w Hr<1	5		IUCLID 5 Study No: [redacted]

	detector response as a function of the isomer concentration. The correlation coefficient (R) of polynomial curve fit for the standard calibrations was greater than 0.99 over the standard calibration range	of the active substance signal or < 3% of the proposed LOQ	respectiv ely)		nomin al At 120% nomin al	103. 6					
1S Trans (S,R)	*Method was not linear* the quadratic function (y = ax2+bx+c) was selected to describe the detector response as a function of the isomer concentration. The correlation coefficient (R) of polynomial curve fit for the standard calibrations was greater than 0.99 over the standard calibration range	No interfering signals are present in the retention time range of the active substance signal or < 3% of the proposed LOQ	80 , 100, 120% of nominal (4.19, 5.0 and 6.16 µg/mL respectiv ely)	3 for each level	At 80% nomin al At 100% nomin al At 120% nomin al	108. 1 103. 7 105. 5		0.335% w/w Hr<1	5		IUCLID 5 Study No: [redacted]
1R Trans (R,S)	*Method was not linear* the quadratic function (y = ax2+bx+c) was selected to describe the detector response as a function of	No interfering signals are present in the retention time range of the	80 , 100, 120% of nominal (7.70, 9.23 and 11.35 µg/mL respectiv ely)	3 for each level	At 80% nomin al At 100% nomin al	107. 2 102. 9		0.821% w/w Hr<1	5		IUCLID 5 Study No: [redacted]

	the isomer concentration. The correlation coefficient (R) of polynomial curve fit for the standard calibrations was greater than 0.99 over the standard calibration range	active substance signal or < 3% of the proposed LOQ			At 120% nominal	105.5					

The average composition of the individual permethrin isomers in RESISTOL 6220

Concentration (% w/w)				
1S Cis (S,S)	1R Cis (R,R)	1S Trans (S,R)	1R Trans (R,S)	Total Permethrin
0.2749	0.1290	0.3242	0.8353	1.5633

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of IPBC residues in air, soil and water have previously been evaluated at EU level and accepted for active substance approval. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic or highly toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure *via* the intended uses.

Methods of analysis for the determination of permethrin residues in air, soil and water have previously been evaluated at EU level and accepted for active substance approval. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic or highly toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure *via* the intended uses.

Methods of analysis for the determination of penflufen residues in soil, air and water have previously been evaluated at EU level and accepted for active substance approval. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic or highly toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure *via* the intended uses.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method *[*21041204G926*]* for the determination of IPBC, permethrin (all isomers) and penflufen in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. Analytical methods for the determination of 2-phenoxy ethanol, Diethylene glycol monophenyl ether and ethoxylated isotridecanol are not submitted as the substances of concern contents are not expected to increase during storage. Methods for the detection of IPBC, permethrin and penflufen in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No other data is required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

MG 02: preservatives
Product Type 08: wood preservative

The product RESISTOL 6220 is water based concentrate which is intended to be used by superficial application for preventative treatment in use classes 1 and 2 of wood (softwood and hardwood) against wood rotting fungi (brown rot fungi), against wood destroying insect (*Hylotrupes bajulus*) and termites (*Reticulitermes spp*).

The application rate recommended by the applicant is 6.46 g RESISTOL 6220 / m² of wood. The product is diluted from 6.46 to 12.92 % v/v prior its application by superficial application by industrial users.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Permethrin is a neurotoxin. It is a synthetic pyrethroid acting after ingestion. The target organisms ingest a small amount of the treated wood which, once ingested, results in death of the target pests. Permethrin when formulated as a wood preservative, is an axonic poison, binding to protein in nerves (voltage-gated sodium channel). Normally, this protein opens causing stimulation of the nerve and closes to terminate the nerve signal. Pyrethroids bind to this gate and prevent it from closing normally which results in continuous nerve stimulation, leading to death. Permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lambda-cyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect (see Assessment Report permethrin, PT08, April 2014). For preventative treatment against wood-boring insects and termites, the effect is immediate, even if efficacy is complete only after a few weeks of exposure of the insects.

Penflufen is an SDHI fungicide (Succinate dehydrogenase inhibitor). Its biochemical mode of action has been shown to rely on the inhibition of the enzyme succinate dehydrogenase (complex II) within the fungal mitochondrial respiratory chain, thus blocking electron transport.

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

3.5.3 Efficacy data

Efficacy studies have been performed with the formulations X10053 and X10054. These formulations differ from the product RESISTOL 6220 because of slight variations on the content of corrosion inhibitor and pH buffer, permethrin is also less concentrated. According to Annex A of EN599, these variations are in the range allowing read-across between the formulations X10053, X10054 and the product RESISTOL 6220 (please refer to the confidential annex).

Table 3.8 Efficacy data

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
PT8 Use 1 Industrial Preventative Treatment	X10053	*Hylotrupes bajulus* larvae	EN 46-1 after EN 73 (evaporation) The product was applied by brushing Six replicate blocks were treated with a preservative concentration of 10% in water to an application rate of 100 ml/m^2 (10 g/m^2 as test product). The actual mean application rate was 99.7 g/m^2 (10 g/m^2 as test product). Three untreated blocks were included as controls Each block was exposed to 10 *Hylotrupes bajulus* larvae. Exposure time in the test was 4 weeks. The effect investigated is mortality of the larvae.	The study is validated as at least 70 % of larvae exposed to the controls survived (96.7%). 100% mortality was recorded for larvae exposed to the test blocks at the end of the test (4 weeks). The biological reference value of the test product after evaporative ageing is 10 g product /m^2.	[redacted] 2019 [redacted] R.I: 1	House longhorn beetle: EN46-1 EN73
PT8 Use 1: Industrial Preventative Treatment	X10054	*Reticulitermes grassei*	EN 118 after EN 73 (evaporation) The product was applied by brushing Six replicate blocks were treated with a preservative concentration of 10% in water to a target application rate of 100 ml/m^2 (10 g/m^2 as test product). The actual mean application rate was 98.2	The study is validated as at the damage rating for each of the control blocks was rated 4 and the corresponding colonies of termites each had at least a 50% survival rate (minimum	[redacted] (2019) [redacted] R.I: 1	Termites: EN118 EN73

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects *[address here results related to efficacy of the test product and validity of the test]*	Reference	Number in IUCLID section 6.7/Test report title
			g/m^2 (9.8 g/m^2 as test product). Three untreated blocks were included as controls Each block was exposed to 250 workers, 5-6 nymphs and 2 soldiers of *Reticulitermes grassei*. Exposure time in the test was 8 weeks. The effect investigated is based on the damage inflicted by the termites on the wood blocks at the over the duratiuon of the test.	in this test: 80%). Visual examination of the test blocks resulted in a rating of 1 in each case. The biological reference value of the test product after evaporative ageing is 9.8 g product/m^2.		
PT8 Use 1: Industrial Preventative Treatment	X10053	*Coniophora puteana* *Gloeophyllum trabeum* *Rhodonia (poria) placenta*	EN 113 after EN 73 (evaporation) The product was applied by vacuum impregnation. The test product was diluted in water to the following product concentrations: 0.37, 0.49, 0.61, 0.71, 0.83% Impregnation at these concentrations was undertaken to achieve the following target retentions in the wood (*Pinus sylvestris* sapwood): 2.8, 3.7, 4.6, 5.4 and 6.3 kg/m^3 Number of replicates: 4 replicates for each treatment and each fungal strain. Untreated controls: one non-treated control block was included with the treated block in each test. Additionally, six virulence control blocks were used for each fungal strain. Blocks were exposed to active cultures of *C. puteana*, *G. trabeum* and *R. placenta*.	The study is validated as more than 20 % of mass loss is observed in the controls for each fungus. *C. puteana*:2.78 kg/m^3 *G. trabeum*: 2.78 – 3.68 kg/m3 mid-toxic value: 3.23 kg/m^3 *R. placenta*: 2.81 kg/m^3 The biological reference value of the test product for brown rot fungi, after evaporative ageing, is 3.23 kg/m^3 equivalent to 6.46 g product/m².	[redacted] (2019) [redacted] R.I: 1	Basidiomycete fungi: EN113 EN73

PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
			Exposure time in the test was 16 weeks. The effect investigated is mass loss of the test blocks caused by fungal decay. The dry mass of individual blocks is recorded at the beginning and at the end of the test.			

3.5.4 Efficacy assessment

- Regarding the claim against wood rotting fungi, according to EN 113 (+EN73), the product X10053 is efficient, for superficial application, against wood rotting fungi (brown rot) for use class 2 at the application rate of 3.23 kg/m3 (equivalent to 6.46 g of product X10053 / m² of wood or 6.46 g RESISTOL 6220 / m² of wood).

- Regarding the preventative efficacy claim against wood boring beetles (*Hylotrupes bajulus*), for superficial application, the product X10053 is efficient according to EN 46 (+EN73), against *Hylotrupes bajulus* for use classes 1 and 2 at the application rate of 10 g of product X10053 / m² of wood equivalent to 4.87 g of product RESISTOL 6220 / m² of wood (in relation to the content of permethrin (please refer to the confidential annex)).

- Regarding the preventative efficacy claim against termites, for superficial application, the product X10054 is efficient according to EN 118 (+EN73), against *Reticulitermes spp*., for use class 1 to 2, at the application rate of 9.8 g of product X10054 / m² of wood equivalent to 6.33 g RESISTOL 6220 / m² of wood (in relation to the content of permethrin (please refer to the confidential annex)).

3.5.5 Conclusion on efficacy

The data submitted in the dossier have demonstrated the efficacy of the product RESISTOL 6220 according to the uses and the application rates claimed.
The product is used for the preventative control of wood boring beetles (*Hylotrupes bajulus*), Termites (*Reticulitermes spp*) and wood destroying fungi (brown rot fungi), in use class 1 and 2 by superficial application.

3.5.6 Occurrence of resistance and resistance management

Resistance to permethrin has been reported for a number of pests both in agriculture and public health (German cockroach (Atkinson et al., 1991), house fly (Shen and Plapp, 1990), stable fly (Cilek and Greena, 1994), Culex mosquitos (Wan-Norafilack et al., 2013), Aedes mosquitos (Saavedra-Rodriguez et al., 2008), Anopheles mosquitos (Müller et al., 2008)…), when permethrin has been used as a general insecticide (PT18 use). In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms (see Assessment Report permethrin, PT08, April 2014).
However, to date, no specific data has been found in the literature regarding occurrence of resistance to permethrin among wood-boring insects and termites.

IPBC has a Carbamate structure. The target sites of Carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).
The risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee. This applies to the use of Carbamate fungicides in agriculture, where yearly applications to the same fields are possible (even more than one application per season is possible).
With regard to the use of Cabamates in wood preservation, resistance formation constitutes an even smaller problem: The number of treatments to a wooden structures is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure.

Penflufen is a new active substance for biocidal purposes. Therefore information on the occurrence of resistance from the use in wood preservation is not available. To date, no specific data has been found in the literature regarding occurrence of resistance to penflufen among wood-boring insects and termites.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

3.5.7 Known limitations

None

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

None

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

There are no human health data available for the product.
The assessment, and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

3.6.1.1 Skin corrosion and irritation

Table 3.9 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant to skin
Justification for the value/conclusion	Specific test data on the formulation is not available, therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.2.3, Annex I: Table 3.2.3 was followed. Details have been provided in confidential annex.
Classification of the product according to CLP	Not classified

3.6.1.2 Eye irritation

Table 3.10 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritant to eyes
Justification for the value/conclusion	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.3.3, Annex I: Table 3.3.3 was followed. Details have been provided in confidential annex.
Classification of the product according to CLP	Eye damage category 1 (H318)

3.6.1.3 Respiratory tract irritation

Table 3.11 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritant to the respiratory tract
Justification for the conclusion	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.3.3, Annex I: Table 3.4.5 was followed. Details have been provided in the confidential annex.
Classification of the product according to CLP	Not classified

3.6.1.4 Skin sensitization

Table 3.12 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin sensitizer
Justification for the value/conclusion	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.3.3, Annex I: Table 3.4.5 was followed. Details have been provided in the confidential annex.
Classification of the product according to CLP	Skin Sensitiser category 1 (H317)

3.6.1.5 Respiratory sensitization

Table 3.13 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitiser
Justification for the value/conclusion	No ingredients are classified for respiratory sensitisation
Classification of the product according to CLP	Not classified

3.6.1.6 Acute oral toxicity

Table 3.14 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	> 2000 mg/kg bw
Justification for the selected value	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.1.3, the calculation under Annex I: 3.1.3.6.1. was followed. Classification by calculation using information from ECHA's C&L Inventory and submitted MSDS. Oral LD_{50} values or converted acute toxicity point estimates used. ATEmix calculated as 4 831 mg/kg bw, this is > 2000 mg/kg, therefore no classification for acute oral toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP	Not classified

3.6.1.7 Acute inhalation toxicity

Table 3.15 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	> 20 mg/l
Justification for the selected value	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.1.3, the calculation under Annex I: 3.1.3.6.2.3 was followed. Classification by calculation using information from ECHA's C&L Inventory and MSDS submitted. Inhalation LC_{50} values or converted acute toxicity point estimates used. ATEmix calculated as 101.5 mg/l, this is > 20 mg/l, therefore no classification for acute inhalation toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP	Not classified

3.6.1.8 Acute dermal toxicity

Table 3.16 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via dermal route
Justification for the selected value	calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.1.3, the calculation under Annex I: 3.1.3.6.1. was followed. No components are classified for this endpoint. Therefore, no classification is proposed for the product.
Classification of the product according to CLP	Not classified

3.6.2 Information on dermal absorption

Table 3.17 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption				
Substance	Permethrin (1.66%)	Penflufen (0.29%)	IPBC (0.66%)	2-phenoxy-ethanol (2.8%)
Value(s)*	3%	50%	50%	50%
Justification for the selected value(s)	Read across (multi-to-one approach in EFSA guidance (2017)[1]. See justification in the Confidental PAR.	Default value for water-based in-use dilutions from EFSA guidance on dermal absorption (2017)[1]	Default value for water-based in-use dilutions from EFSA guidance on dermal absorption (2017)[1]	Default value for water-based in-use dilutions from EFSA guidance on dermal absorption (2017)[1]

1. EFSA. 2017. Guidance on dermal absorption. EFSA Journal ; 15(6) : 4873

3.6.3 Available toxicological data relating to substance(s) of concern

According to the criteria as set in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)), the following substances need to be considered as substances of concern regarding human health:

Table 3.18 Available toxicological data relating to substances of concern

Substance of concern	Criterion for the identification as a substance of concern	Band	Type of risk assessment performed
2-phenoxyethanol (CAS 122-99-6)	BPR, Art. 3 (f)	C	Quantitative risk assessment using Biocides endpoints (CAR data)
Diethylene glycol monophenyl ether (CAS 104-68-7)	BPR, Art. 3 (f)	B	Qualitative risk assessment
Ethoxylated isotridecanol (CAS 69011-36-5)	BPR, Art. 3 (f)	B	Qualitative risk assessment

3.6.4 Other

3.6.4.1 Food and feeding stuffs studies

Not relevant

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant

3.6.4.3 Other test(s) related to the exposure to humans

Not relevant

3.6.5 Available toxicological data relating to endocrine disruption

The biocidal product contains the active substances "Penflufen", "Permethrin" and "IPBC" which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, none of the co-formulants contained in the family are regulatory identified as endocrine disruptors or have significant ED properties.

Please refer to the Confidential Annex and the embedded Excel file for further details.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

RESISTOL 6220 is a soluble concentrate (SL) formulation containing 0.29 % w/w penflufen, 1.66 % w/w permethrin and 0.66% IPBC as active substances.
The product is intended for professional use in industrial settings only.

Overview of the proposed application methods for 'Resistol 6220'

Application method	Dilution	Maximum in-use concentration	Retention rate[1]
Automated dipping	6.46 – 12.92%	0.037 % w/w penflufen 0.21 % w/w permethrin 0.085% w/w IPBC 0.362 % w/w 2-phenoxyethanol (SoC)	6.46 g concentrated pb/m^2: 0.0187 g penflufen/m^2 0.107 g permethrin/m^2 0.043 g IPBC/m^2 0.181 g 2-phenoxyethanol/m^2 (SoC)
Deluge / enclosed spray treatment			

[1] The retention rate is expressed in g/m^2 as the product is applied by superficial application processes only

Relevant guidance documents consulted for human health risk assessment

- Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017;
- Biocides Human Health Exposure Methodology Document (BHEEM);
- TNsG 2002, Human Exposure to Biocidal Products – Guidance on Exposure Estimation;
- HEEG opinion Nos 8 and 9;
- HEAdhoc recommendation Nos 6 and 14.

Relevant exposure models or exposure studies used for human health risk assessment

- TNsG Handling Model 1;
- TNsG Dipping Model 1;
- ConsExpo Web version 1.0.7.

Strategy for human health risk assessment

For penflufen, permethrin, IPBC and 2-phenoxyethanol, the mode of action is systemic hence a quantitative risk assessment is completed using toxicological endpoints set under BPR.
In addition, a qualitative risk assessment is completed for local effects based on the hazard classification of the concentrate (H317 and H318).

The product 'RESISTOL 6220' is intended for professional use in industrial settings only.
For primary exposure, each application method is assessed separately.
For secondary exposure, the amount of product retained on the wood is relevant to exposure. As this is identical for both superficial application methods, the secondary exposure assessment presented is relevant to both application methods (automated dipping and deluge treatment).

Resistol is intended to be used for UC1 and UC2 treated wood only (i.e., wood that is not exposed to weather, largely used for framing and roof timbers).

Considerations on volatility of the active substance(s) and substance(s) of concern

The vapour pressure of the active substances are as follows:

- IPBC: 2.36-4.5 x 10^{-3} Pa at 25°C (AR, 2008);
- Permethrin: 2.155 x 10^{-6} Pa at 20°C (AR, 2014);
- Penflufen: 4.1 x 10^{-7} Pa at 20°C (AR, 2017).

None of the active substances are considered volatile therefore inhalation exposure to vapour is not estimated.

2-phenoxyethanol (identified as a SoC) is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C (AR, 2018). Inhalation exposure to vapours is therefore estimated as a worst case approach.

Strategy for livestock exposure and/or dietary risk assessment

Not relevant

Strategy for the assessment of substance(s) of concern

The product 'RESISTOl 6220' contains 2.8 % w/w 2-phenoxyethanol (CAS 122-99-6), which is a Biocidal active substance with agreed toxicological reference values (AR, 2018).
The quantitative risk assessment is conducted using the endpoints from the Assessment Report.

The product 'RESISTOL 6220' also contains diethylene glycol monophenyl ether (CAS 104-68-7) and ethoxylated isotridecanol (CAS 69011-36-5).
These are identified as Band B substances of concern therefore a qualitative assessment is completed in the risk characterisation.

Strategy for disinfectant by-products assessment

Not relevant.

3.6.6.2 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the biocidal product

Table 3.19 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
	Primary (direct) exposure		**Secondary (indirect) exposure**		
Exposure path	**Professional users** (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/General public**	**Via food**
Oral	No	n/a	No	Yes	No
Dermal	Yes	n/a	Yes	Yes	No
Inhalation	Yes	n/a	Yes	Yes	No

3.6.6.3 List of exposure scenarios

Table 3.20 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group** (e.g. professionals, non-professionals, professional bystanders, non-professional bystanders/general public)
Primary exposure		
Scenario [1]	**Automated mixing/loading**	Professional in industrial setting
Scenario [2]	**Application - Automated dipping/immersion of wooden articles**	Professional in industrial setting
Scenario [3]	**Application - Automated deluging/flow coating/aspersion**	Professional in industrial setting
Scenario [4]	**Post-application – Handling of treated wooden articles**	Professional in industrial setting
Scenario [5]	**Post-application – Cleaning of the system**	Professional in industrial setting
Secondary exposure		
Scenario [6]	**Non-Professional adult sanding treated wood**	General public
Scenario [7]	**Toddler mouthing treated off-cut of wood**	General public
Scenario [8]	**Professional adult sanding treated wood**	Professional
Scenario [9]	**Child playing on a playground structure outdoors**	General public
Scenario [10]	**Infant playing on a weathered structure and mouthing**	General public
Scenario [11]	**Inhalation of volatilised residues**	Professional and General public
Combined secondary exposure		
Scenarios [8+11]	**Professional adult sanding treated wood and inhaling volatilised residues**	
Scenarios [10+11]	**Infant playing on a weathered structure and mouthing and inhaling volatilised residues**	

3.6.6.4 Reference values to be used in risk characterisation

Table 3.21 Reference values to be used in risk characterisation

Penflufen

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	Acute neurotoxicity	50 mg/kg bw/d	167	n/a	0.3 mg/kg bw/d
AELmedium-term	1 year dog	7.7 mg/kg bw/d	100	n/a	0.077 mg/kg bw/d
AELlong-term	2 year rat	4 mg/kg bw/d	100	n/a	0.04 mg/kg bw/d
ARfD	Acute neurotoxicity	50 mg/kg bw/d	100	n/a	0.5 mg/kg bw/d
ADI	2 year rat	4 mg/kg bw/d	100	n/a	0.04 mg/kg bw/d

Permethrin

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	2 year rat (acute effect)	50 mg/kg bw/d	100	n/a	0.5 mg/kg bw/d
AELmedium-term	12 month dog	5 mg/kg bw/d	100	n/a	0.05 mg/kg bw/d
AELlong-term	12 month dog	5 mg/kg bw/d	100	n/a	0.05 mg/kg bw/d
ARfD	2 year rat (acute effect)	50 mg/kg bw/d	100	n/a	0.5 mg/kg bw/d
ADI	12 month dog	5 mg/kg bw/d	100	n/a	0.05 mg/kg bw/d

IPBC

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	90-day gavage rat	35 mg/kg bw/d	100	n/a	0.35 mg/kg bw/d
AELmedium-term	90-day gavage rat	35 mg/kg bw/d	100	n/a	0.35 mg/kg bw/d
AELlong-term	2-years rat	20 mg/kg bw/d	100	n/a	0.2 mg/kg bw/d
ARfD	90-day gavage rat	35 mg/kg bw/d	100	n/a	0.35 mg/kg bw/d
ADI	2-years rat	20 mg/kg bw/d	100	n/a	0.2 mg/kg bw/d

2-phenoxyethanol (SoC)

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
Oral route					
AEL short-term	90-day drinking water rat	370 mg/kg bw/d	100	n/a	0.37 mg/kg bw/d
AEL medium-term	90-day drinking water rat	370 mg/kg bw/d	100	n/a	0.37 mg/kg bw/d
AEL long-term	2-years drinkind water rat	250 mg/kg bw/d	100	n/a	0.25 mg/kg bw/d
ADI	2-years drinkind water rat	250 mg/kg bw/d	100	n/a	0.25 mg/kg bw/d
ARfD	90-day drinking water rat	370 mg/kg bw/d	100	n/a	0.37 mg/kg bw/d
Dermal route					
AEL short-term	90-d dermal rabbit study	375 mg/kg bw/d	25	n/a	15 mg/kg bw/d
AEL medium-term	90-d dermal rabbit study	375 mg/kg bw/d	25	n/a	15 mg/kg bw/d
AEL long-term	90-d dermal rabbit study	375 mg/kg bw/d	50	n/a	7.5 mg/kg bw/d
Inhalation route					
AEC short-term	14-d inhalation rat study	48.2 mg/m^3	25	n/a	1.93 mg/m^3
AEC medium-term	14-d inhalation rat study	48.2 mg/m^3	75	n/a	0.64 mg/m^3
AEC long-term	14-d inhalation rat study	48.2 mg/m^3	150	n/a	0.32 mg/m^3

3.6.6.5 Specific reference value for groundwater

Not relevant.

3.6.6.6 Professional users (including industrial users and trained professional users)

The product 'RESISTOL 6220' is applied by professional users in industrial settings only. Primary exposure is *via* dermal and inhalation routes.

Scenario [1]: [Automated Mixing and loading]

Description and input parameters

Table 3.22 Description and input parameters

Description of Scenario [1]
The concentrated product Resistol 6220 is supplied in bulk (HDPE IBCs) of 640 and 1000L and transfer is automated *via* dedicated transfer lines. The dosing and mixing process is fully automated and conducted within a closed system without direct human involvement. Therefore exposure associated with this task is considered negligible compared to other related tasks (i.e. the application phase) and does not need to be included as a source of exposure according to HEEG Opinion 1.

Scenario [2]: [Application - Automated dipping/immersion of wooden articles]

Description and input parameters

Table 3.23 Description and input parameters

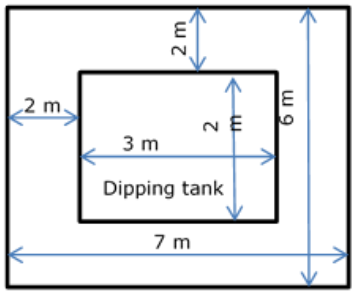
Description of Scenario [2]
The product RESISTOL 6220 containing 0.29% penflufen, 1.66% permethrin and 0.66% IPBC is used for wood preservation by automated dipping in an industrial setting (chronic exposure). According to the applicant, the product is diluted in water with dilution rate of 6.46 – 12.92%. The maximum in-use concentrations have been calculated as follows: - 0.037% penflufen; - 0.21% permethrin; - 0.085% IPBC; - 0.362% 2-phenoxyethanol (identified as SoC). Automated dipping includes the following operations: An operator using a fork-lift truck or similar equipment lowers the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for a few minutes or for a few hours before being lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. The operator exposure arises from handling of the treated wood. To assess exposure during this task, the *Handling model 1*, from TNsG Part 2 is used according to the HEAd Hoc recommendation 6 (2020).

The indicative values from the model are as follows:
- 1080 mg/cycle hands inside gloves);
- 8570 mg/cycle (body).

The duration default value of exposure for automated dipping is 4 cycles of 60 minutes per day (HEEG Opinion (8), 2009).

HEEG Opinion 8 states that inhalation exposure resulting from aerosol formation should be negligible. When the low vapour pressure of penflufen, permethrin and IPBC are also considered, exposure due to inhalation is considered negligible for active substances. However, 2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20°C. Exposure to vapour is therefore estimated using the *Evaporation model* from ConsExpo.

It is considered a dipping tank of 3m x 2m. As a worst case, air concentration is calculated for workers within 2m of the tank. Hence, the room size for modelling is considered as 7m long x 6m large x 2.5 height.



Input parameters for Scenario [2]			
Dermal exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Active substances conentrations in the dipping liquid	- 0.037% penflufen; - 0.21% permethrin; - 0.085% IPBC; - 0.362% 2-phenoxyethanol	Applicant's data (considering a 12.92% dilution)
	Indicative values	- 1080 mg/cycle (hands inside gloves); - 8570 mg/cycle (body).	HEAd hoc Recommendation 6
	Number of cycles	4	HEEG Opinion 8
	Dermal absorption value - Permethrin	3%	See section 3.6.2
	Dermal absorption values – Penplufen, IPBC, 2-phenoxyethanol	50%	See section 3.6.2
	Body weight (kg)	60	HEAd hoc Recommendation 14
Tier 2	Clothing penetration factor (impermeable coverall)	5%	HEEG Opinion 9

Inhalation exposure to vapour			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Active substance concentration in the dipping liquid	0.362% 2-phenoxyethanol	Applicant's data (considering a 12.92% dilution)
	Room size (m^3)	105 (7m long x 6m large x 2.5 height)	See above
	Dipping tank size (m^2)	6	See above
	Ventilation rate	0.6/h	General Fact sheet - Default value for unspecified room
	Inhalation rate (m^3/h)	1.25	HEAd hoc Recommendation 14
	Inhalation absorption value	100%	Default value

Scenario [3]: [Application - Automated deluging/flow coating/aspersion]

Description and input parameters

Table 3.24 Description and input parameters

Description of Scenario [3]
The product Resistol 6220 containing 0.29% penflufen, 1.66% permethrin and 0.66% IPBC is used for wood preservation by automated deluging/flow coating/aspersion in an industrial setting (chronic exposure). Wood is passed through an enclosed tunnel where a wood preservative is sprayed on the timber. Due to its contained nature, operator exposure is expected to be low, and mainly constitutes handling freshly sprayed wood. The *Dipping model 1* from BHEEM is the proposed exposure model for professional deluging in HEAdhoc Recommendation no. 6 (2020). Deluging processes are operated on a batch basis, assuming as a worst case one batch per day, with a duration of 60 minutes per event. The indicative values from the model are as follows: - 25.7 mg/min (hands inside gloves); - 178 mg/min (body); - < 1 mg/m^3 (inhalation of low volatile-susbtances). 2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20°C. Exposure to vapour is therefore estimated using the *Evaporation model* from ConsExpo. As a worst-case approach, the results from the scenario above (dipping tank) are used. It is assuemed that inhalation exposure to wooden articles during is at least equal or lower than inhalation exposure to evaporation from a dipping tank during 240 min. For details, please refer to the scenario above.

Input parameters for Scenario [2]			
Dermal exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Active substances concentrations in the dipping liquid	- 0.037% penflufen; - 0.21% permethrin; - 0.085% IPBC; - 0.362% 2-phenoxyethanol	Applicant's data (considering a 12.92% dilution)
	Indicative values	- 25.7 mg/min (hands inside gloves); - 178 mg/min (body); - < 1 mg/m^3 (inhalation)	HEAd hoc Recommendation 6
	Treatment duration	60 min	HEAd hoc Recommendation 6
	Dermal absorption value - Permethrin	3%	See section 3.6.2
	Dermal absorption values – Penplufen, IPBC, 2-phenoxyethanol	50%	See section 3.6.2
	Body weight (kg)	60	HEAd hoc Recommendation 14
Tier 2	Clothing penetration factor (coated coverall)	10%	HEEG Opinion 9
Inhalation exposure to vapour			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Active substance concentration in the dipping liquid	0.362% 2-phenoxyethanol	Applicant's data (considering a 12.92% dilution)
	Room size (m^3)	105 (7m long x 6m large x 2.5 height)	See above
	Dipping tank size (m^2)	6	See above
	Ventilation rate	0.6/h	General Fact sheet - Default value for unspecified room
	Inhalation rate (m^3/h)	1.25	HEAd hoc Recommendation 14
	Inhalation absorption value	100%	Default value

Scenario [4]: [Post-application – Handling of treated articles]

Description and input parameters

Exposure from handling of treated articles may occur after the application process.
This scenario is covered by the exposure calculations as presented for scenario [2], which covers application and post application processes (*Handling model 1* for water-based products, BHEEM).

Scenario [5]: [Post-application – Maintenance/cleaning of the system]

Description and input parameters

Potential exposure may occur during maintenance, testing/repair of the automated application system (hoses, valves, connecting lines, etc.).
In these cases, contamination could occur by the dermal route.
However, such tasks are expected to be rare and of short duration, and, additionaly, the pumping/transfer system is assumed to be decontaminated before maintenance work is performed.
The rationale for not considered eventual exposure during the Mixing and loading task is considered applicable to the tasks in this scenario.

Cleaning of the application systems is also a potential source of exposure, and varies between industries/automated processes.
According to HEEG Opinion no. 18 (TM III, 2013), a survey of 24 companies found that dipping tanks were cleaned with frequencies ranging from twice a year (only one company) to every fifth year. At 19 companies, the cleaning was performed by in-house workers, thus this task can be considered relevant.
There is no generic model for cleaning of industrial dipping tanks, though *Handling Model 1* (identified in HEAdhoc Recommendation no. 6, version 4, May 2020, as an appropriate model for intermittent handling of water-wet wood and associated equipment), can be used as a surrogate.
Therefore, the exposure values from Scenario [2] Application by automated dipping (in which Handling Model 1 was used) can be considered applicable.

Outcome of systemic exposure and risk characterisation

Table 3.25 Summary table: estimated systemic exposure and risk characterisation for professional users

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Penflufen							
Chronic exposure (AEL LT = 0.04 mg/kg bw/d)							
Scenario [2]	1/Gloves*	-	1.19E-01	-	1.19E-01	298	**NO**
	2/Gloves + impermeable coverall	-	1.86E-02	-	1.86E-02	47	Yes
Scenario [3]	1/Gloves*	-	3.77E-02	7.71E-06	3.77E-02	94	Yes
	2/Gloves + coated coverall	-	8.06E-03	7.71E-06	8.06E-03	20	Yes
Acute exposure (AEL ST = 0.3 mg/kg bw/d)							
Scenario [5]	1/Gloves*	-	1.19E-01	-	1.19E-01	40	Yes
	2/Gloves + impermeable coverall	-	1.86E-02	-	1.86E-02	6	Yes
Permethrin							
Chronic exposure (AEL LT = 0.05 mg/kg bw/d)							
Scenario [2]	1/Gloves*	-	4.05E-02	-	4.05E-02	81	Yes
	2/Gloves + impermeable coverall	-	6.34E-03	-	6.34E-03	13	Yes

Scenario [3]	1/Gloves*	-	1.28E-02	4.38E-05	1.29E-02	26	Yes
	2/Gloves + coated coverall	-	2.74E-03	4.38E-05	2,78E-03	6	Yes
Acute exposure (AEL ST = 0.5 mg/kg bw/d)							
Scenario [5]	1/Gloves*	-	4.05E-02	-	4.05E-02	8	Yes
	2/Gloves + impermeable coverall	-	6.34E-03	-	6.34E-03	1	Yes
IPBC							
Chronic exposure (AEL LT = 0.2 mg/kg bw/d)							
Scenario [2]	1/Gloves*	-	2.73E-01	-	2.73E-01	137	**NO**
	2/Gloves + impermeable coverall	-	4.27E-02	-	4.27E-02	21	Yes
Scenario [3]	1/Gloves*	-	8.66E-02	1.77E-05	8.66E-02	43	Yes
	2/Gloves + coated coverall	-	1.85E-02	1.77E-05	1.85E-02	9	Yes
Acute exposure (AEL ST = 0.35 mg/kg bw/d)							
Scenario [5]	1/Gloves*	-	2.73E-01	-	2.73E-01	78	Yes
	2/Gloves + impermeable coverall	-	4.27E-02	-	4.27E-02	12	Yes
2-phenoxyethanol							
Chronic exposure (AEL LT = 7.5 mg/kg bw/d)							
Scenario [2]	1/Gloves*	-	1.16E+00	8.56E-4	1.17E+00	16	Yes
	2/Gloves + impermeable coverall	-	1.82E-01	8.56E-4	1.83E-01	2	Yes
Scenario [3]	1/Gloves*	-	3.69E-01	8.56E-4	3.70E-01	5	Yes
	2/Gloves + coated coverall	-	7.87E-02	8.56E-4	7.96E-02	1	Yes
Acute exposure (AEL ST = 15 mg/kg bw/d)							
Scenario [5]	1/Gloves*	-	1.16E+00	8.56E-4	1.17E+00	8	Yes

	2/Gloves + impermeable coverall	-	4.27E-02	-	4.27E-02	1	Yes

* The model used provides an indicative value for hands is ‘inside gloves’, thus use of gloves is considered at Tier 1.

Combined scenarios

No relevant combined scenarios are identified for industrial uses on the basis that:

a) chronic exposure from two or more sources is not expected to occur (it is assumed that only a single application task will be performed daily;
b) Mixing and loading (transfer form product packs to application equipment) is fully automated, resulting in negligible exposure;
c) occasional exposure during maintenance/testing of the application system is considered negligible compared to that during the application phase, such that occasional (~ once-yearly) cleaning of the dipping tank is the only relevant acute exposure.

Theoretically, automated dipping (a chronic exposure) and cleaning of the dipping tank (an acute exposure) could be performed by the same worker on the same day.
In this regard, Point 'TOX 37' for PT8 of the Technical Agreements for Biocides (TAB) – TOX v.2.0 (of 09.11.2018) states: "*exposure during the application and post-application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term scenario"*. As the cleaning task is a rare event, the combination of the two tasks can be evaluated as an acute exposure.

Outcome of (semi-)quantitative local exposure and risk characterisation

Table 3.26 Summary table: estimated systemic exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³]**	**Estimated exposure / AEC (%)**	**Acceptable (yes/no)**
2-phenoxyethanol						
Chronic exposure (AEC LT = 0.32 mg/m³)						
Scenario [2]	1/no PPE	-	8.56E-4	8.56E-4	3.22	Yes
Scenario [3]	1/no PPE	-	8.56E-4	8.56E-4	3.22	Yes
Chronic exposure (AEC ST = 1.93 mg/m³)						
Scenario [5]	1/no PPE	-	8.56E-4	8.56E-4	0.53	Yes

Outcome of qualitative local risk assessment

The concentrated product RESISTOL 6220 is proposed to be classified Skin sens.1 – H317 and Eye Dam.1 – H318 based on the content of actives substances and co-formulants.
Considering the intended dilution rate of 12.92%, the in-use dilution of the product is not classified (see confidential Annex).

Table 3.27 Outcome of qualitative local risk assessment

Hazard		Exposure information					Risk			
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
Very High	**H317**	**8**	Automated addition of concentrated product into the system (dipping tank)	**Skin**	**Frequency**1 /day **Duration :** 15 min	For automated process, direct contact with contaminated surfaces	Use of appropriate personal protective equipment: Hand protection: gloves Eye protection: goggles Body protection: Protective clothing	Labelling: - Labelling according to CLP Professionals: - Professional workers Instructions for use minimizing exposure for professionals	**Acceptable**	(↑) High hazard category (↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low frequency (↓) Minimization of manual phases (process automation)
	H318			**Eye**						

Conclusion

For application of the product by automated dipping, the risk is acceptable considering the wear of PPE (gloves, impermeable coverall and goggles).

For application by automated deluging/flow coating or aspersion, the risk is acceptable considering the wear of PPE (gloves, coated coverall and goggles).

For the cleaning of the systems, the risk is acceptable considering the wear of PPE (gloves, impermeable coverall and goggles).

3.6.6.7 Non-professional users

The product is intended to be used by industrial users only.

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

RESISTOL 6220 is a wood-preservative product intended to be used only in industrial settings.
Concerning secondary exposure to professional bystanders and non-professional bystanders/general public, the following scenarios have to be taken into consideration:

Acute phase reference scenarios:
- Adult – cutting and sanding treated wood (non-professional);
- Infant – chewing wood off-cut.

Chronic phase reference scenarios:
- Adult - cutting and sanding treated wood (professional);
- Adult, child, infant – inhalation of volatilized residues indoors;
- Child – playing on playground structure outdoors;
- Infant – playing on weathered structure and mouthing.

Scenario [6]: [Adult – cutting and sanding treated wood (non-professional)]

Description and input parameters

Table 3.28 Description and input parameters

Description of Scenario [6]
Non-professional exposure to the product RESISTOL 6220 can occur during the cutting and sanding of treated wooden articles. Dermal and inhalation exposure are considered during this task. The application rate intended by the applicant is 6.46 g pb/m^2. As main assumption, the product is assumed to be retained in a 1 cm layer at the surface of the wooden article. The concentration in active substances in the product to be taken into account are as follows: - 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC. 2-phenoxyethanol is identified as a SoC in the product. However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure can occur.

Input parameters for Scenario [6]			
	Parameters[1]	**Value**	**Reference and justification[3]**
	Active substances concentrations in the product	- 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC.	Applicant's data
	Application rate	6.46 g pb/m^2	Applicant's data
	Volume of wooden article	44 000 cm^3 (4 cm x 4 cm x 250 cm)	User Guidance 2008
	Layer of timber	1 cm	User Guidance 2008
	Wood density	0.4 g/cm^3	User Guidance 2008
	Body weight	60 kg	HEAd hoc Recommendation 14
Dermal exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Fraction of dislodgeable residues	3%	BHHEM (p.171), for painted wood – dried fluid
	Surface area in contact with wood (two palms)	410 cm^2	HEAd hoc Recommendation 14
	Dermal absorption value (Penflufen and IPBC)	50%	Default value according to EFSA Guidance 2017
	Dermal absorption value (Permethrin)	3%	See Confidential Annex.
Inhalation exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Dust concentration in air	5 mg/m^3	Occupational exposure limit for wood dust (User Guidance 2008)
	Exposure duration	1 h	TNsG 2002, Part 3 (p.50), for acute exposure
	Inhalation rate	1.25 m^3/h	HEAd hoc Recommendation 14
	Wood dust density	0.8 g/cm^3	TNsG 2002, Part 3 (p.50)
	Inhalation absorption (Penflufen, Permethrin, IPBC)	100%	Default values

Scenario [7]: [Infant – Chewing wood off-cut]

Description and input parameters

Table 3.29 Description and input parameters

Description of Scenario [7]
An infant may be exposed to the product *via* oral route when chewing a chip from a wooden article previously treated with the product. The application rate intended by the applicant is 6.46 g pb/m^2. The concentration in active substances in the product to be taken into account are as follows: - 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC. 2-phenoxyethanol is identified as a SoC in the product. However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure can occur.

Input parameters for Scenario [7]			
	Parameters[1]	**Value**	**Reference and justification[3]**
	Active substances concentrations in the product	- 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC.	Applicant's data
	Application rate	6.46 g pb/m^2	Applicant's data
	Volume of wooden article	416 cm^3 (4 cm x 4 cm x 1 cm)	User Guidance 2008
	Body weight	8 kg	HEAd hoc Recommendation 14
Oral exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Fraction of residues extracted from the wooden chip	10%	TNsG 2002, Part 3 (p.50)
	Oral absorption values (Penflufen, Permethrin and IPBC)	100%	Active substances data

Scenario [8]: [Adult – cutting and sanding treated wood (professional)]

Description and input parameters

Table 3.30 Description and input parameters

Description of Scenario [8]
Indirect professional exposure to the product RESISTOL 6220 can occur during the cutting and sanding of treated wooden articles. Dermal and inhalation exposure are considered during this task. The application rate intended by the applicant is 6.46 g pb/m^2. As main assumption, the product is assumed to be retained in a 1 cm layer at the surface of the wooden article. The concentration in active substances in the product to be taken into account are as follows: - 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC. 2-phenoxyethanol is identified as a SoC in the product. However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure can occur.

Input parameters for Scenario [8]			
	Parameters[1]	**Value**	**Reference and justification[3]**
	Active substances concentrations in the product	- 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC.	Applicant's data
	Application rate	6.46 g pb/m^2	Applicant's data
	Volume of wooden article	44 000 cm^3 (4 cm x 4 cm x 250 cm)	User Guidance 2008
	Layer of timber	1 cm	User Guidance 2008
	Wood density	0.4 g/cm^3	User Guidance 2008
	Body weight	60 kg	HEAd hoc Recommendation 14
Dermal exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Fraction of dislodgeable residues	3%	BHHEM (p.171), for painted wood – dried fluid
	Surface area in contact with wood (two palms)	410 cm^2	HEAd hoc Recommendation 14
	Dermal absorption value (Penflufen and IPBC)	50%	Default value according to EFSA Guidance 2017
	Dermal absorption value (Permethrin)	3%	See Confidential Annex.
Inhalation exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Dust concentration in air	5 mg/m^3	Occupational exposure limit for wood dust (User Guidance 2008)
	Exposure duration	6 h	TNsG 2002, Part 3 (p.50), for acute exposure
	Inhalation rate	1.25 m^3/h	HEAd hoc Recommendation 14
	Wood dust density	0.8 g/cm^3	TNsG 2002, Part 3 (p.50)
	Inhalation absorption (Penflufen, Permethrin, IPBC)	100%	Default values

Scenario [9]: [Child – playing on playground structure outdoors]

Description and input parameters

Table 3.31 Description and input parameters

Description of Scenario [9]
A child may be exposed to the product RESISTOL 6220 when playing outdoor on a playground structures previously treated. Dermal exposure is considered in this scenario. The application rate intended by the applicant is 6.46 g pb/m^2. The concentration in active substances in the product to be taken into account are as follows: - 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC. 2-phenoxyethanol is identified as a SoC in the product. However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure can occur. According to the intended uses claimed by the applicant, Resistol is used for UC1 and UC2 treated wood only (i.e., wood that is not exposed to weather, largely used for framing and roof timbers). Use under conditions where exposure to weather occurs, including uses for playgrounds or fences for livestock enclosures, are not anticipated (these are associated with UC3). However, for completeness, secondary exposure scenarios for an outdoor use have been developed.

Input parameters for Scenario [9]			
	Parameters[1]	**Value**	**Reference and justification[3]**
	Active substances concentrations in the product	- 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC.	Applicant's data
	Application rate	6.46 g pb/m^2	Applicant's data
	Body weight	15.6 kg	HEAd hoc Recommendation 14
Dermal exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Fraction of dislodgeable residues	3%	BHHEM (p.171), for painted wood – dried fluid
	Surface area in contact with wood	200 cm^2	User Guidance 2008
	Contaminated area	20%	User Guidance 2008
	Dermal absorption value (Penflufen and IPBC)	50%	Default value according to EFSA Guidance 2017
	Dermal absorption value (Permethrin)	3%	See Confidential Annex.

Scenario [10]: [Infant – playing on playground structure outdoors and mouthing]

Description and input parameters

Table 3.32 Description and input parameters

Description of Scenario [10]
An infant may be exposed to the product RESISTOL 6220 when playing outdoor on a playground structures previously treated. Dermal and oral exposure are considered in this scenario due to the hand to mouth transfer that is taken into consideration for infant. The application rate intended by the applicant is 6.46 g pb/m^2. The concentration in active substances in the product to be taken into account are as follows: - 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC. 2-phenoxyethanol is identified as a SoC in the product. However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure can occur. According to the intended uses claimed by the applicant, Resistol is used for UC1 and UC2 treated wood only (i.e., wood that is not exposed to weather, largely used for framing and roof timbers). Use under conditions where exposure to weather occurs, including uses for playgrounds or fences for livestock enclosures, are not anticipated (these are associated with UC3). However, for completeness, secondary exposure scenarios for an outdoor use have been developed.

Input parameters for Scenario [10]			
	Parameters[1]	**Value**	**Reference and justification[3]**
	Active substances concentrations in the product	- 0.29% penflufen; - 1.66% permethrin; - 0.66% IPBC.	Applicant's data
	Application rate	6.46 g pb/m^2	Applicant's data
	Body weight	8 kg	HEAd hoc Recommendation 14
Dermal exposure			
	Parameters[1]	**Value**	**Reference and justification[3]**
Tier 1 (no PPE)	Fraction of dislodgeable residues	3%	BHHEM (p.171), for painted wood – dried fluid
	Surface area in contact with wood	200 cm^2	User Guidance 2008
	Contaminated area	20%	User Guidance 2008
	Dermal absorption value (Penflufen and IPBC)	50%	Default value according to EFSA Guidance 2017
	Dermal absorption value (Permethrin)	3%	See Confidential Annex.
Oral exposure			
Tier 1 (no PPE)	Amount of surface deposit ingested	100%	User Guidance 2008
	Oral absorption values (Penflufen, Permethin and IPBC)	100%	Active substances data

Scenario [11]: [Adult, Child, Infant – Inhaling volatilised residues]

Description and input parameters

Table 3.33 Description and input parameters

Description of Scenario [11]
Adults, children and toddlers can be exposed to volatilised residues of active substances after the application of the product on wooden surfaces. In the HEEG Opinion 13 on "the Assessment of Inhalation Exposure of Volatilised Biocide Active Substance", a calculation is developed to determine if the risk from inhalation exposure is negligible or should be included in the risk assessment. This formula is based on the parameters of the toddler representing the worst-case and covering every other age group: $$0.328 * \frac{mw * vp}{AEC\ long - term}$$ With mw being the molecular weight and vp the vapour pressure. If the result is below 1, then the risk from inhalation exposure is considered negligible. The following parameters are used for the approach in Tier 1: For Penflufen: - Mw = 317.41 g/mol - Vp = 4.1×10^{-7} Pa (20°C) - $AEL_{long\text{-}term}$ = 0.04 mg/kg bw/d For Permethrin: - Mw = 321.29 g/mol - Vp = 2.16×10^{-6} Pa (20°C) - $AEL_{long\text{-}term}$ = 0.05 mg/kg bw/d For IPBC: - Mw = 281.1 g/mol - Vp = 2.36×10^{-3} Pa (20°C) - $AEL_{long\text{-}term}$ = 0.2 mg/kg bw/d For Penflufen and permethrin, the inhalation exposure is considered negligible after the application of the product and is not taken into account in the risk assessment. 2-phenoxyethanol is identified as a SoC in the product. However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure can occur. Only inhalation exposure to volatilised residues of IPBC is considered relevant and a human health risk is identified for toddler. Hence, exposure assessment was refined for this active substance using the *Evaporation model* From Consexpo. The product amount was calculated from the application rate (6.46 g /m^2) and an application surface (or release area) of 8 m^2. The product being intended to be applied on wood and constructional timbers , this surface is considered as a realistic worst case for a room with a volume of 20 m^3 and a height of 2.5 m (Default room volume acc. to Consexpo General Fact Sheet, 2012). As a very worst case approach the vapor pressure value at 25°C (4.5×10^{-3} Pa) is taken into account for IPBC.

	Parameters	**Value**	**Reference and justification**
Tier 2 (for IPBC	Product amount for treatment of 8 m^2	51.7 g	Applicant's application rate x treated surface

only)			(6.46g/m^2 x 8 m^2)
	Concentration IPBC	0.085%	See above
	Vapour pressure IPBC	2.36 x 10^{-3} Pa at 20°C 4.5 x 10^{-3} Pa at 20°C	CAR/AR, 2008
	Room volume	20 m^3	(default, Consexpo General Fact Sheet, 2012)
	Ventilation rate	0.6/h	(Consexpo General Fact Sheet, 2012)
	Realease area	8 m^2	See above

Outcome of systemic exposure and risk characterisation

Table 3.34 Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Penflufen							
Acute exposure (AEL ST = 0.3 mg/kg bw/d)							
Scenario [6]	1/without PPE	-	1,92E-04	6,54E-07	1,93E-04	0.064	Yes
Scenario [7]	1/without PPE	1,12E-03	-	-	1,12E-03	0.37	Yes
Chronic exposure (AEL LT = 0.04 mg/kg bw/d)							
Scenario [8]	1/without PPE	-	1,92E-04	6,54E-07	1,93E-04	0.48	Yes
Scenario [9]	1/without PPE	-	7,21E-05	-	7,21E-05	0.18	Yes
Scenario [10]	1/without PPE	3,51E-04	1,41E-04	-	4,92E-04	1.23	Yes
Scenario [11]	1/without PPE	-	-	negligible	negligible	n.a	Yes
Permethrin							
Acute exposure (AEL ST = 0.5 mg/kg bw/d)							
Scenario [6]	1/without PPE	-	6,60E-05	3,74E-06	6,97E-05	0.014	Yes
Scenario [7]	1/without PPE	6,43E-03	-	-	6,43E-03	1.29	Yes
Chronic exposure (AEL LT = 0.05 mg/kg bw/d)							

Scenario [8]	1/without PPE	-	6,60E-05	3,74E-06	6,97E-05	0.14	Yes
Scenario [9]	1/without PPE	-	2,47E-05	-	2,47E-05	0.05	Yes
Scenario [10]	1/without PPE	2,01E-03	4,83E-05	-	2,06E-03	4.12	Yes
Scenario [11]	1/without PPE	-	-	negligible	negligible	n.a	Yes
IPBC							
Acute exposure (AEL ST = 0.35 mg/kg bw/d)							
Scenario [6]	1/without PPE	-	4,37E-04	1,49E-06	4,39E-04	0.125	Yes
Scenario [7]	1/without PPE	2,56E-03	-	-	2,56E-03	0.73	Yes
Chronic exposure (AEL LT = 0.2 mg/kg bw/d)							
Scenario [8]	1/without PPE	-	4,37E-04	1,49E-06	4,39E-04	0.22	Yes
Scenario [9]	1/without PPE	-	1,64E-04	-	1,64E-04	0.08	Yes
Scenario [10]	1/without PPE	7,99E-04	3,20E-04	-	1,12E-03	0.56	Yes
Scenario [11] *Adult*	1/without PPE	-	-	7,25E-02	7,25E-02	36.3	Yes
Scenario [11] *Child*	1/without PPE	-	-	1,76E-01	1,76E-01	88.05	Yes
Scenario [11] *Toddler*	1/without PPE	-	-	2,18E-01	2,18E-01	108.8	No
	2/without PPE (with ConsExpo)	-	-	4.6E-04	4.6E-04	0.23	Yes
Scenario [11] *Infant*	1/without PPE	-	-	1,88E-01	1,88E-01	94.2	Yes

Combined scenarios

Outcome of combined systemic exposure and risk characterisation

Table 3.35 Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Penflufen							
Chronic exposure (AEL LT = 0.04 mg/kg bw/d)							
Scenario [8 + 11]	1/without PPE	-	1,92E-04	6,54E-07	1,92E-04	0.48	Yes
Scenario [10 + 11]	1/without PPE	3,51E-04	1,41E-04	negligible	1,41E-04	0.35	Yes
Permethrin							
Chronic exposure (AEL LT = 0.05 mg/kg bw/d)							
Scenario [8 + 11]	1/without PPE	-	6,60E-05	3,74E-06	6,60E-05	0.13	Yes
Scenario [10 + 11]	1/without PPE	2,01E-03	4,83E-05	negligible	4,83E-05	0.1	Yes
IPBC							
Chronic exposure (AEL LT = 0.2 mg/kg bw/d)							
Scenario [8 + 11]	1/without PPE	-	4,37E-04	7,40E-02	5,11E-04	36.48	Yes
Scenario [10 + 11]	1/without PPE	7,99E-04	3,20E-04	1,88E-01	5,08E-04	94.34	Yes

Outcome of (semi-)quantitative local exposure and risk characterisation

2-phenoxyethanol is identified as a SoC in the product.
However, due to the volatility of the substance (Vp = 1 Pa) and the function as a solvent in the formulation, it is assumed that it is already evaporated and no secondary exposure is expected to occur.

Outcome of qualitative local risk assessment

The product RESISTOL 6220 is used at dilution rate 6.46 – 12.92%.
The maximum in-use concentration of the product (dilution rate at 12.92%) is not classified (see confidential Annex).

Conclusion

The risk is considered acceptable for professional bystanders and general public after the application of the product RESISTOL 6220.

3.6.7 Monitoring data

Not relevant

3.6.8 Dietary risk assessment

The intended use description of the product RESISTOL 6220 indicates that this use is not relevant in terms of residues in food and feed. However, to prevent any food or feed contamination, the following risk mitigation measures are added:

- Do not use on wood which may come in direct contact with food feeding stuff and livestock animals;
- The person responsible for placing the treated wood on the market must ensure that the treated wood is not intended for uses involving contact with food, feed or livestock.

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Penfuflen is a Plant Protection active substance approved under Regulation 1107/2009 and permethrin is a non-approved active substance under Regulation 1107/2009 and approved under Regulation 37/2010 (Veterinary Medical Product). The Maximum Residue Limits have been included below.

Table 3.36 Summary table of other (non-biocidal) uses

	Sector of use	Reference value(s)	Regulation
Penflufen			
	Plant Protection Products	0.01 mg/kg Default MRL for all commodities	(EC) No 396/2005
Permethrin			
	Veterinary Medical Products	Bovine Muscle 50 µg/kg Fat 500 µg/kg Liver 50 µg/kg Kidney 50 µg/kg Milk 50 µg/kg For milk further provisions in Commission Directive 98/82/EC are to be observed.	COMMISSION REGULATION (EU) No 37/2010

3.6.8.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

Not relevant considering intended use.

3.6.8.3 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

Not relevant considering intended use.

3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

Not relevant considering intended use.

3.6.8.5 Maximum residue limits or equivalent

See table 3.72 above.

3.6.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

RESISTOL 6220 contains 3 active substances (Penflufen, Permethrin and IPBC) and 1 SoC (2 phenoxyethanol) with systemic effects.
A risk characterization from combined exposure to those substances within the product is performed in accordance with the Guidance on the BPR: Volume III Human Health (Parts B+C).

Tier 1 and tier 2

Table 3.37 Tier 1 and tier 2

Scenario [2] Primary exposure	**Penflufen**	**Permethrin**	**IPBC**	**2-phenoxyethanol**	**Conclusions**
Without PPE					
Tier 1	*298% AEL*	*81% AEL*	*137% AEL*	*16% AEL*	***Not Acceptable***
Tier 2	*2,98*	*0,81*	*1,37*	*0,16*	***Not acceptable***
	HI = 5,31				
With Gloves and impermeable coverall					
Tier 1	*47% AEL*	*13% AEL*	*21% AEL*	*2% AEL*	*Acceptable*
Tier 2	*0,47*	*0,13*	*0,21*	*0,02*	*Acceptable*
	HI = 0.83				

Scenario [3] Primary exposure	**Penflufen**	**Permethrin**	**IPBC**	**2-phenoxyethanol**	**Conclusions**
Without PPE					
Tier 1	*94% AEL*	*26% AEL*	*43% AEL*	*5% AEL*	*Acceptable*
Tier 2	*0,94*	*0,26*	*0,43*	*0,05*	***Not acceptable***
	HI = 1.68				
With Gloves and coated coverall					
Tier 1	*20% AEL*	*6% AEL*	*9% AEL*	*1% AEL*	*Acceptable*
Tier 2	*0,20*	*0,06*	*0,09*	*0,01*	*Acceptable*
	HI = 0.36				

Scenario [5] Primary exposure	**Penflufen**	**Permethrin**	**IPBC**	**2-phenoxyethanol**	**Conclusions**
Without PPE					
Tier 1	*40% AEL*	*8% AEL*	*78% AEL*	*8% AEL*	*Acceptable*
Tier 2	*0,40*	*0,08*	*0,78*	*0,08*	***Not acceptable***
	HI = 1.34				
With Gloves and impermeable coverall					
Tier 1	*6% AEL*	*1% AEL*	*12% AEL*	*1% AEL*	*Acceptable*
Tier 2	*0,06*	*0,01*	*0,12*	*0,01*	*Acceptable*
	HI = 0.21				

Scenario [6] & [8] Secondary exposure	Penflufen	Permethrin	IPBC	Conclusions
Acute				
Tier 1	*0,0642% AEL*	*0,0139% AEL*	*0,1253% AEL*	*Acceptable*
Tier 2	*0,0006*	*0,0001*	*0,0013*	*Acceptable*
	HI = 0.002			
Chronic				
Tier 1	*0,48% AEL*	*0,14% AEL*	*0,22% AEL*	*Acceptable*
Tier 2	*0,0048*	*0,0014*	*0,0022*	*Acceptable*
	HI = 0.0084			

Scenario [7] Secondary exposure	Penflufen	Permethrin	IPBC	Conclusions
Acute				
Tier 1	*0,3747% AEL*	*1,2868% AEL*	*0,7309% AEL*	*Acceptable*
Tier 2	*0,0037*	*0,0129*	*0,0073*	*Acceptable*
	HI = 0.024			

Scenario [9] Secondary exposure	Penflufen	Permethrin	IPBC	Conclusions
Chronic				
Tier 1	*0,18% AEL*	*0,05% AEL*	*0,08% AEL*	*Acceptable*
Tier 2	*0,0018*	*0,0005*	*0,0008*	*Acceptable*
	HI = 0.0031			

Scenario [10] Secondary exposure	Penflufen	Permethrin	IPBC	Conclusions
Chronic				
Tier 1	*1,23% AEL*	*4,12% AEL*	*0,56% AEL*	*Acceptable*
Tier 2	*0,01*	*0,04*	*0,01*	*Acceptable*
	HI = 0.06			

Scenario [8+11] Secondary exposure	Penflufen	Permethrin	IPBC	Conclusions
Chronic				
Tier 1	*0,48% AEL*	*0,13% AEL*	*36.5% AEL*	*Acceptable*
Tier 2	*0,0048*	*0,0013*	*0.36*	*Acceptable*
	HI = 0.37			

Scenario [10+11] Secondary exposure	Penflufen	Permethrin	IPBC	Conclusions
Chronic				
Tier 1	*0,35% AEL*	*0,10% AEL*	*94.34% AEL*	*Acceptable*
Tier 2	*0,0035*	*0,0010*	*0,94*	*Acceptable*
	HI = 0.95			

3.6.10 Overall conclusion on risk assessment for human health

Table 3.38 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
[1]	Industrial Preventative Treatment Application by **Dipping** Preventative treatment of wood and constructional timbers in Use Classes 1 & 2. The product can be applied to both softwood and hardwood	Acceptable with the following RMMs.	During the application of the product and the cleaning of the systems: - Wear protective chemical resistant gloves (glove material to be specified by the autorisation holder within the product information); - Wear an impermeable protective coverall (coverall material to be specified by the autorisation holder within the product information); - Wear chemical goggles.
	Industrial Preventative Treatment Application by **Deluge/Enclosed spray** Preventative treatment of wood and constructional timbers in Use Classes 1 & 2. The product can be applied to both softwood and hardwood	Acceptable with the following RMMs.	During the application of the product and the cleaning of the systems: - Wear protective chemical resistant gloves (glove material to be specified by the autorisation holder within the product information); - Wear a coated protective coverall (coverall material to be specified by the autorisation holder within the product information); - Wear chemical goggles.

[1] Use numbers in accordance with the list of all uses indicated under section 2.2.
[2] Title of the specific use, as indicated in the SPC
[3] For the wording of the RMMs, refer to the "Frequently used sentences in the SPC and translations" available at https://echa.europa.eu/support/dossier-submission-tools/spc-editor. The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2

3.7 Risk assessment for animal health

3.7.1 Risk for companion animals

No specific risk assessment has been performed for companion animals.

It is considered covered by the assessment performed for General public, especially infant and toddler.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for companion animals, if the directions for use, as specified in the SPC, are followed.

3.7.2 Risk for livestock animals

Not relevant

3.8 Risk assessment for the environment

The product RESISTOL 6220 is a ready-to-use solvent-based wood preservative containing 0.66% w/w of IPBC, 1.66% w/w of Permethrin and 0.29% w/w of Penflufen. It is intended to be applied in industrial plants for wood used indoor (classified as use classes 1 and 2). According to the Emission Scenario Document for wood preservatives (PT08), "for wood of UC 1 and 2 emission pathways are presented but no scenarios, since for these wood classes the potential emissions from treated wood to the outer environment are considered negligible".

Therefore, no risk assessment has been performed for the service-life phase of this product.

Nevertheless, in order to prevent any releases during the industrial application phase, the following risk mitigation is proposed:

- Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber
- All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
- Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal'
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

Not relevant.

3.8.1.2 Endpoints for the product

There are no new additional data available for the product.

3.8.1.3 Substance of concern

According to the criteria as set in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)), the following substance needs to be considered as a substance of concern regarding the environment:

Table 3.39 Substance(s) of concern

Substance of concern	Criterion for the identification as a substance of concern	Type of risk assessment performed
2-phenoxyethanol	Active substance in PT 1, 2, 4, 6 & 13	Not relevant because the product is intented for wood of UC 1 and 2 which does not require a risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

3.8.2 Emission estimation

3.8.2.1 General information

The industrial application phase is covered by the following risk mitigations measures:

- Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber
- All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
- Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal'
- Any contaminated water/soil shall be collected, contained and treated as hazardous waste

For the service-life, as explained above, no scenarios are presented for wood of use classes 1 and 2, since for these wood classes the potential emissions from treated wood to the outer environment are considered negligible.

3.8.3 Primary and secondary poisoning

3.8.3.1 Primary poisoning

As the product is intented to be use indoor for wood of UC 1 and 2, an assessment for primary poisoning is not relevant.

3.8.3.2 Secondary poisoning

As the product is intented to be use indoor for wood of UC 1 and 2, an assessment for secondary poisoning is not relevant.

3.8.4 Mixture toxicity

Not relevant.

3.8.5 Aggregated exposure (combined for relevant emission sources)

Not relevant.

3.8.6 Overall conclusion on the risk assessment for the environment

Table 3.40 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment
The biocidal product RESISTOL 6220 is intended to be used in industrial plant only for indoor uses (wood classes 1 and 2); therefore, the industrial application phase of this product is covered by risk mitigation measures and the service-life is not considered to pose any risk for the environment.

3.9 Assessment of a combination of biocidal products

Not relevant

3.10 Comparative assessment

The biocidal product contains permethrin which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: persistent (P) and toxic (T).

No comparative assessment was performed as according to the document CA-June22-Doc.4.2, a comparative assessment in accordance with Article 23 should only be carried out when an active substance is identified as meeting the substitution criteria in the renewal of approval Regulation with regards to Article 10 (5) of the BPR and when this status is validated by ECHA's Biocidal Product Committee (BPC).

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Exposure assessment calculation files are not presented in this version of the annex.
For access to the files, please contact directly the eCA (helpdesk-biocides@anses.fr).

4.2 New information on the active substance(s) and substance(s) of concern

No new information on the substance of concern is available

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
[redacted]	2021	3.1 Appearance (at 20°C and 101.3 kPa)	Appearance / physical state / colour.001	Title: Determination of the accelerated storage of (Resistol 6220 according to CIPAC MT 46.3 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	3.2 Acidity, alkalinity	pH	Title: Determination of the accelerated storage of (Resistol 6220 according to CIPAC MT 46.3 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	3.3 Relative density (liquids) and bulk, tap density (solids)	Density	Title: Determination of the Density of Resistol 6220 according to OECD 109 and method EU A.3 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes

				[redacted]				
[redacted]	2021	3.4.1 Storage stability tests	Accelerated Storage Stability	Title: Determination of the accelerated storage of (Resistol 6220 according to CIPAC MT 46.3 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	3.4.1 Storage stability tests	Low temperature stability	Title: Determination of the stability of liquid formulations of Resistol 6220 at 0°C according to CIPAC MT 39.3 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	3.5 Technical characteristics of the biocidal product	Persistent Foaming	Title: Determination of the persistent foaming of Resistol 6220 according to CIPAC MT 47.3 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	3.7 Degree of dissolution and dilution stability	Degree of dissolution and dilution stability.001	Title: Determination of the accelerated storage of (Resistol 6220 according to CIPAC MT 46.3	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes

[redacted]				[redacted]				
[redacted]	2021	3.8 Surface tension	Surface tension.001	Title: Determination of the surface tension of an aqueous solution of Resistol 6220 according to OECD 115 and EU A.5 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	3.9 Viscosity	Viscosity.001	Title: Determination of Viscosity of · Resistol 6220 according to OECD 114 I DIN 53015 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	4.6 Flammable liquids	Flash point.001	Title: Determination of the flash point of Resistol 6220 according to EU Method A9, OPPTS 830.6315 and Section 32.4, UN Manual of Tests and Criteria [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	4.16 Corrosive to metals	Corrosive to metals.001	Title: Determination of the corrosion to metals by Resistol 6220	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes

				[redacted]				
[redacted]	2021	4.17.1 Auto-ignition temperature (liquids and gases)	Auto flammability.001	Title: Determination of the auto ignition temperature of Resistol 6220 according to EU A.15 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2022	4.8 Self-Reactive substances and mixtures	Self-Reactive substances and mixtures.001	Title: Self-Reactive Properties Screening on a Test Item of Resistol 6220 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	5 Methods of detection and identification	Analytical methods.001	Title: Validation of an Analytical Method using HPLC-UV for the determination of Penflufen, Permethrin and IPBC in Resistol 6220 based on SANC0/3030/99 rev. 5 [redacted]	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes
[redacted]	2021	5 Methods of detection and identification	Permethrin chirality method	Title: Analytical Method Validation for teh Analysis of Permethrin Isomersin Vacsol Aqua 6118,	study report	Arch Timber Protection Limited	yes (incl. QA statement)	Yes

				Endseal 3444 and Resistol 6220 [redacted]				

4.4 Confidential information

Please refer to the separate document Confidential Annex of the PAR.