Product Assessment Report

Olej kreozotowy gatunek B
Olej kreozotowy gatunek C

Biocidal product assessment report related to national authorisation under Biocidal Product Regulation 528/2012

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1 General information about the product family application

1.1 Applicant

Company Name:	Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o.
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1.1.1 Person authorised for communication on behalf of the applicant

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1.2 Current authorisation holder

Not applicable.

1.3 Proposed authorisation holder

Company Name:	Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o.
Address:	8 Wrocławska Str.
City:	Bytom
Postal Code:	41-902
Country:	Poland
Telephone:	+48 32 281 46 46 +48 32 281 71 43
Fax:	-
E-mail address:	daw@daw.bytom.pl
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	n.a.

1.4 Information about the product application

Application received:	30.04.2013
Application reported complete:	03.03.2014
Type of application:	Application for national authorisation of a biocidal product family
Further information:	n.a.

1.5 Information about the biocidal product family

1.5.1 General information

Trade name:	*Olej kreozotowy gatunek B* *Olej kreozotowy gatunek C*
Manufacturer's development code number(s), if appropriate:	No code assigned
Product type:	8 (Wood preservatives)
Composition of the product (identity	Creosote 100%

and content of active substance(s) and substances of concern; full composition see confidential annex):	
Formulation type:	Oily liquid
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	Yes, The Active substance and the biocidal product creosote both fulfil the criteria as described in European Standard EN 13991. Because of the UVCB nature of creosote variation is inevitable.

1.5.2 Information on the intended use proposed by applicant[1]

Overall use pattern (manner and area of use):	Outdoor use
Target organisms:	1) Wood rotting fungi: ✓ wood rotting basidiomycetes, ✓ soft rot micro-fungi, ✓ wood disfiguring fungi. 2) Wood rot in soil and water contact. 3) Insects: ✓ Termites, ✓ wood-decaying beetles. 4) Marine crustacea and molluscs (marine borers).
Category of users:	Professional and industrial use only

[1] **Please note that although different uses of creosote are considered in assessment presented in this PAR, it does not mean that Applicant has proved lack of appropriate alternatives for creosote for all of these uses (please refer to Annex 8).**

Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	1) Vacuum-pressure impregnation 2) Hot-and-cold open tank (bath) method 3) Brush treatment of wooden constructions Efficient doses: • Use class 3: o 50-120 kg/m^3 for softwood o 20-150[2] kg/m^3 for hardwood • Use class 4: o 76-137 kg/m^3 for softwood o 39-139 kg/m^3 for hardwood • Use class 5: o 156-400 kg/m^3 for softwood o 156-400 kg/m^3 for hardwood
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes
Use Restrictions:	According to applicants submission, biocidal product family can be used for the following applications: 1) impregnation of wooden sleepers and poles, 2) impregnation in an agricultural sector e.g. fruit tree and hop/vineyard stakes, fences, anti-hail curtains, 3) horse fences, 4) noise (highway) barriers, 5) snow barriers, 6) marine installations (harbor wharf). However, according to Polish authorisation, biocidal product family can be used only for the following applications: 1) impregnation of wooden sleepers and poles, 2) impregnation in an agricultural sector e.g. fruit tree and hop/vineyard stakes,

[2] in case of railway sleepers higher retention – up to 180 kg/m^3 is required

	fences, anti-hail curtains. Please refer also to section 2.5.4 and Annex 8

1.5.3 Information on active substance

Active substance chemical name:	Creosote
CAS No:	8001-58-9
EC No:	232-287-5
Purity (minimum, g/kg or g/l):	1000 g/kg (UVCB substance)
Inclusion directive:	2011/71/UE
Date of inclusion:	1 May 2013
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes

Manufacturer of active substance used in the biocidal product family

Company Name:	Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o.
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City:	Bytom
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1.5.4 Information on the substance(s) of concern

Creosote is a complex mixture of hundreds of distinct compounds, including bi- and polycyclic aromatic hydrocarbons, phenols, as well as heterocyclic, oxygen-, sulphur- and nitrogen-containing compounds. 106 compounds have been identified in the creosote mixture under evaluation (see Table 1.1-2 in DOCII-A of the CAR).

Hence, the concept of substances of concern is not applicable in this case.

1.6 Documentation

1.6.1 Data submitted in relation to product application

The active substance is identical to the biocidal product family. That was why no separate data for the biocidal product family was prepared.

Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o. has its own source of active substance, therefore data necessary to evaluation of technical equivalence were presented and the report on technical equivalence was prepared by PL CA.

There are certificates of analysis submitted to confirm 10-years storage stability period.

There are also new data generated for active substance and they are presented in this Product Assessment Report. Please see Annex 1.

1.6.2 Access to documentation

Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o. became a member of Creosote Council Europe on April 17^{th} 2013 and thus became a data owner of all CCE data, jointly developed and owned by CCE members. This data was used to includes active substances on the Union list of approved active substances (formerly Annex I of Directive 98/8/EC).

Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o. has its own source of active substance which its considered to be technically equivalent to the source(s) from the list of approved active substances.

2 Summary of the product family assessment

2.1 Identity related issues

The biocidal product family *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* consists of the active substance Creosote Grade B and C. Creosote is a complex mixture of hundreds of different compounds, including bi- and polycyclic aromatic hydrocarbons, phenols, as well as heterocyclic oxygen-, sulphur- and nitrogen-containing compounds. Due to the complex composition of creosote it falls under the definition of a substance of Unknown or Variable composition, Complex reaction products or Biological materials (i.e. an UVCB-substance, purity is not applicable).

The European creosotes must comply with the criteria in the European Standard EN 13991:2003. The results for test batches of the product *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* are summarized in the table 2.1.

Table 2.1 Identification parameters associated with criteria set out in European Standard EN 13991:2003

		Specification for creosote EN 13991:2003 Criteria		**Analysis results from Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o.**	
Properties	**unit**	**Grade B**	**Grade C**	***Olej kreozotowy gatunek B***	***Olej kreozotowy gatunek C***
Density (20 ºC)	g/ml	1.02-1.15	1.03-1.17	1.06	1.10
Water content	%	Max. 1	Max. 1	0.51	0.07
Crystallization temperature	ºC	Max. 23	Max. 50	11	37
Water extractable phenols	%	Max. 3	Max. 3	0.55	0.01
Matter insoluble in toluene	%	Max. 0.4	Max. 0.4	0.14	0.02
Boiling range: Distillate to 235 ºC Distillate to 300 ºC Distillate to 355 ºC	 % % %	 Max. 20 40-60 Min. 70	 Max.10 Min. 65	 4.1 55 88	- - 86
Benzo[a]pyrene	ppm	Max. 50	Max. 50	18.45	7.97
Flash point Pensky-Martens	ºC	Min. 61	Min. 61	122	166

The source of active substance used in the biocidal product is technically equivalent to the source(s) from the list of approved active substances.

2.2 Classification, labelling and packaging

2.2.1 Classification of creosote according to the CLP Regulation 1272/2008/EC

Carc. 1B; H350 May cause cancer.

Repr. 1B; H360F May damage fertility.

Repr. 2; H361d Suspected of damaging the unborn child.

Skin Irrit. 2; H315 Causes skin irritation.

Skin Sens. 1; H317 May cause an allergic skin reaction.

Aquatic acute 1; H400 Very toxic to aquatic life.

Aquatic chronic 1; H410 Very toxic to aquatic life with long lasting effects M=10.

2.2.2 Labelling of the product family according to the CLP Regulation 1272/2008/EC

Pictograms	 GHS07
	 GHS08
	 GHS09
Signal word	Danger
Hazard statements	H315 Causes skin irritation.
	H317 May cause an allergic skin reaction.
	H350 May cause cancer.
	H360F May damage fertility.
	H361d Suspected of damaging the unborn child.
	H410 Very toxic to aquatic life with long lasting effects.

Precaution statements	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P272 Contaminated work clothing should not be allowed out of the workplace. P308+ P313 IF exposed or concerned: Get medical advice/attention. P332+P313 If skin irritation occurs: Get medical advice/attention. P405 Store locked up. P501 Dispose of contents/container to an approved waste facility for hazardous wastes.

2.2.3 Packaging of the biocidal products

The packaging details for the biocidal product family, *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C*, are outlined below for professional and industrial users.

Packing type	Pack sizes for professional and industrial use
Stainless steel bulk container for transport by road, rail or sea*	250 - 700 000 L
Plastic IBC container	250 - 1000 L
Stainless Steel IBC container	250 - 1000 L
Stainless drums	50 - 250 L
Metal cans (coated tin plate cans)	>20 L

* not actual commercial packaging type – these containers are for transport only and not for storage for long periods of time.

2.3 Physical-chemical properties and analytical methods

2.3.1 Physical-chemical properties

Physical-chemical properties of the active substance:

Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o. is co-owner of data which was used to support the Annex I listing of the active substance creosote according to Directive 98/8/EC therefore no additional information for this point is needed.

Physical-chemical properties of the biocidal products:

The biocidal product is identical to the active substance; please see Document IIA in the CAR, Table 1.3-1.

Data set of physical-chemical properties of the products *Olej kreoztowy gatunek B* and *Olej kreozotowy gatunek C* required for determination of technical equivalence was submitted.

Applicant has provided a certificates of analysis for 10 and 17 years old creosote products stored at ambient temperature. The results confirm the stability of the product. The proposed shelf-life claim of 10 years at ambient temperature is therefore considered justified.

2.3.2 Analytical methods

Please note that the product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* is the same as the active substance, therefore analytical methods are identical to those described for the active substance in DocIII-A4 and DOCII-A of the CAR.

2.3.3 Analysis of the active substance as manufactured

The method provided for characterisation of the creosote under evaluation is based on GC-FID and it was able to determine 65%, 63% and 57% (w/w) of the total content in the Grade B-composite, Grade B and Grade C respectively.

No validation data was provided for the method except for some linearity data. However, due to the complex nature of creosote and as it falls under the definition of substances of unknown or variable composition, complex reaction products or biological materials (i.e. a UVCB-substance) according to the REACH Implementation Project (RIP) 3.10 no further validation data is considered required.

Nevertheless, provided characterisation data on the US-types P1/13 and P2 creosote indicates higher analytical closures. However, during the peer-review it was decided that it is not considered justified requiring further data as it is not anticipated to significantly improve the characterisation of the creosote under evaluation.

2.3.3.1 Formulation analysis

See above. The active substance and the product family are the same.

2.3.3.2 Residue analysis

The active substance and the product family are identical. Analytical methods for the determination of the major components of creosote in relevant environmental matrices were provided during the Annex I inclusion of creosote (see DOC III A4.2 of CAR).

<u>Soil and sediment</u>

For soil the applicant stated that the provided US-EPA standard for extraction of PAHs, phenols and heterocycles could be used in connection with any of the methods used for characterisation of creosote. However, the RMS in CAR considers that some validation data is required in support of this statement and therefore proposes that this should be set as a data requirement.

Additional data has been submitted at the product family authorisation stage to verify the applicability of the extraction procedure and extraction efficiency for the determination of PAHs in soil. The extraction procedure was assessed by the use of certificated reference material (ERM®CC013a). The PAHs in the reference material were extracted under the conditions to be applied on the test samples. The recovery of the PAHs in the reference material was acceptable (>60% recovery) when the uncertainty of the certified values and measurement uncertainty were taken into account. The analytical results from reference material support the applicability of the extraction method.

2.4 Risk assessment for physical-chemical properties

The processing and application of creosote implies no particular risks when handled as specified. Creosote has a significant vapour pressure which rises rapidly with increasing temperature therefore storage and work places have to be sufficiently ventilated. It is stable at elevated temperatures, it is not flammable (flash point >80–105°C) and not self-igniting with an ignition temperature above 450°C. Creosote has no oxidising properties.

2.5 Effectiveness against target organisms

2.5.1 Function

According to applicant submission the biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* is intended be used as a wood preservative in preventive treatment, outdoor, in use classes 3, 4 and 5.

Olej kreozotowy gatunek B and Olej kreozotowy gatunek C are the same as the active substance creosote and it is used against wood rotting fungi, wood rot in soil and water contact, and against insects (repellent, fungicide, insecticide): The European Standard EN 350-2 (CEN 1994) lists the relative durabilities of selected wood species to groups of wood-destroying fungi, dry wood-destroying beetles and termites.

The product family is intended major for treatment of timber by vacuum-pressure impregnation. Additionally, applicant declared two non-pressure methods of application:

- Treatment of wooden stakes/posts by a non-pressure method – the immersion technique for wood preservation which has minor importance as compared with the vacuum-pressure impregnation process, but it allows to impregnate only part of a wooden post which are preferentially used in agriculture and horticulture.
- Brush treatment of wooden constructions – best practice to treat wood in its final form after all cutting, shaping and machining has been carried out so that the protective envelope of preservative is not broken. This is often achieved but in some cases modifications of wood components after treatment are necessary (by cutting, boring or shaping) and in such cases a suitable preservative must be applied, typically by brush, to protect any surfaces exposed by such works. Such preservative must be compatible with the original treatment and a brush-applied grade of creosote is needed for this.

2.5.2 Organisms to be controlled

1) Wood rotting fungi (wood rotting basidiomycetes, soft rot micro-fungi, wood disfiguring fungi);
2) Wood rot in soil and water contact;
3) Insects (termites, wood-decaying beetles).
4) Marine crustaceæ and molluscs (marine borers).

2.5.3 Dose / mode of action

The product family is identical as the active substance. New efficacy studies have not been submitted and the efficacy evaluation is based on information presented in CAR (please see table 2.2).

Applicant proposed following efficient doses of the product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C:*

- Use class 3:
  - 50-120 kg/m^3 for softwood
  - 20-150 kg/m^3* for hardwood
- Use class 4:
  - 76-137 kg/m^3 for softwood
  - 39-139 kg/m^3 for hardwood
- Use class 5:
  - 156-400 kg/m^3 for softwood
  - 156-400 kg/m^3 for hardwood

* in case of railway sleepers higher retention – up to 180 kg/m^3 is required

Table 2.2 Experimental data on the effectiveness of the active substance creosote against target organisms (presented in CAR).

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test guidelines	Test results: effects, mode of action, resistance	Reference
Creosote Grade C	*Lentinus* (*Basidiomycete*)	Lab-test: Prior accelerated ageing / wood decay / pine and beech / 16 weeks / 28 °C	EN 84 + EN 73 (ageing) EN 113, Feb. 1986 (CEN 1997, 1988 1996b)	≤40 kg oil/m^3 wood (amount to prevent a weight loss of ≥3% in 16 weeks)	Komora, 1999; Boenigk *et al*., 1996
Creosote Grade B	*Lentinus* (*Basidiomycete*)	Lab-test: Wood decay / pine / accelerated ageing / 4 week biological treatment / 22°C oil retention: 33.5-293 kg/m^3	DIN 52176-1, Sep. 1972	Approx. 110 kg oil/m^3 wood (amount to prevent a weight loss ≥2% in 16 weeks)	Wälchli, 1983
Creosote Grade C	Soil microflora	Lab-test: Wood rot assay / Pine and beech / in vermiculite	ENV 807 (CEN 2001a)	≤86 kg oil/m^3 wood	Komora, 1999; Boenigk *et al*., 1996
Creosote, EU (acid-free creosote not specified)	*Basidiomycetes*	Lab-test: Impregnated pine pieces / various oil loadings / 4 weeks	DIN 52176-1, Sep. 1972	≤15-~20 kg oil/m^3 wood (amount to prevent a weight loss ≥2% in 16 weeks)	Willeitner, 1975
Creosote German	*Basidiomycetes*	Lab-test: Impregnated pine pieces / various oil loadings / 4 weeks	DIN 52176 before Sep. 1972 (Aug. 1939)	5-~28 kg oil/m^3 wood (amount to prevent a weight loss of >5% in 16 weeks)	Becker, 1950

Creosote German	Insects: beetles (*Xylophaga*)	Lab-test: Impregnated pine pieces / various oil loadings / 12 weeks	DIN 52623 (beetles)	27-28 kg oil/m^3 wood	Becker, 1950
Creosote German	Insects: beetles (*Anobia*)	Lab-test: Impregnated pine pieces / various oil loadings / 12 weeks	DIN 52623 (beetles)	25-43 kg oil/m^3 wood	Becker, 1950
Coal tar creosote WEI Type B and Scand. standards 1936	Boring mussels (*Teredinidae*)	Field study: pine and birch / 2 locations (North Sea, Baltic Sea) / 3 oil loadings / 10 years	NWPC Standard No. 1.4.2.2./73	100% protection: ~360 kg/m^3 wood >85% protection at ~160 kg/m^3 (outer layer)	NWPC, 1993

Although some of the efficacy data are old, they nevertheless, together with many years of practical experience, adequately show the good efficiency of creosote against a broad spectrum of harmful organisms.

The oil loads of different oil cuts that proved to be effective for the control of beetles, such as anobia and xylophaga larvae, ranged from 10 to 40 kg/m^3 as well as of the basidiomycete *Lentinus* at about 25 kg/m^3. The laboratory results are consistent with observations in field studies (Becker, 1950). For the brown-rot fungus *Coniophora* and white-rot fungus *Polystictus*, respectively, 12-20 kg/m^3 of all variants of the oil tested reduced the wood loss below 2%, but *Lentinus* showed the highest resistance of the organisms tested, associated with a vague cut-off limit for toxicity (Willeitner, 1975). Under test conditions, 110 kg/m^3 are the minimum inhibitory concentration to achieve a weight loss of less than 2%. These results are largely consistent with former observations with this organism: all inhibitory oil loads were in the range of 70-90 kg/m^3 .There was no significant influence of phenols on the efficacy of the different oils. The decisive factors are the content of higher-boiling fractions and the fact that tar-oil consists of numerous fungicidal compounds (Wälchli, 1983).

In CAR for creosote it was stated, that in order to achieve full efficacy for marine applications, much higher oil retention (i.e. ≥300 kg/m^3) will be required even though a retention of 40–150 kg/m^3 wood was originally intended to cover also use class 5 applications.

Applicant has submitted following data concerning efficacy in UC5:

Zahora *et al* (2000) reports tests with panels of Southern pine sapwood exposed in the sea at Queensland, Australia. After 70 months panels treated with creosote at 200 and 400 kg/m^3 (target retentions) were protected with the lower retention panels having a slightly lower rating (more damage).

Rhatigan *et al* (2000) reports tests with panels of Southern pine sapwood exposed in the sea at Newport, Oregon USA. After 70 months panels treated with creosote at target retentions of 200 and 400 kg/m^3 were protected.

The data supports application rate for penetrating treatment against target organisms with *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* declared by applicant.

For the above reasons Polish Competent Authority considers the data to be acceptable in support of *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C*.

Please note also that although different uses of creosote are considered in the efficacy assessment it does not mean that applicant has proved lack of appropriate alternatives for creosote for all of these uses (please refer to Annex 8).

2.5.4 Known limitations

According to Commission Directive 2001/90/EC of 26 October 2001 adapting to technical progress for the seventh time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (creosote):

1) May not be used in the treatment of wood. Furthermore, wood so treated may not be placed on the market,
2) However by way of derogation:
    (a) Relating to the substances and preparations: these may be used for wood treatment in industrial installations or by professionals covered by Community legislation on the protection of workers for *in-situ* tretreatment only if they contain:
        a. benzo-a-pyrene at a concentration of less than 0.005% by mass

b. and water extractable phenols at a concentration of less than 3% by mass.

Such substances and preparations for use in wood treatment in industrial installations or by professionals:

— may be placed on the market only in packaging of a capacity equal to or greater than 20 litres,

— may not be sold to consumers.

Without prejudice to the application of other Community provisions on the classification, packaging and labeling of dangerous substances and preparations, the packaging of such substances and preparations shall be legibly and indelibly marked "For use in industrial installations or professional treatment only".

(b) Relating to wood treated in industrial installations or by professionals according to (i) which is placed on the market for the first time or retreated *in-situ*: this is permitted for professional and industrial use only, e.g. on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (e.g. stakes for tree support) and in harbours and waterways.

(c) Relating to wood having been treated with creosote to (i) before this Directive applies: the prohibition in point 1 on the placing on the market shall not apply where this is placed on the second-hand market for re-use.

3) However, treated wood referred to under point 2 (ii) and (iii) may not be used:

- inside buildings, whatever their purpose,
- in toys,
- in playgrounds,
- in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact,
- in the manufacture of garden furniture such as picnic tables,
- for the manufacture and use and any re-treatment of:
  a. containers intended for growing purposes,
  b. packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption,
  c. other materials which may contaminate the products mentioned above.

2.5.5 Resistance

No resistance is known. During the long history of the use of tar oils (creosote) as wood-preserving agent (more than 150 years), this material has preserved its effectiveness against wood-decay and destruction. Development of "resistance" against an active substance implies a selection of an enrichment process for specialists, which – combating them successfully – would require increasing amounts of the "drug" or introduction of a new alternative. Neither occurred with creosote: The specific amounts per volume wood, that have been efficient and commonly been used since the technical introduction of creosote for wood preservation, have decreased or remained constant rather than increased over time. Hence, there is no evidence of development of resistance, at least not of that inheritable type that is stable over pest generations and expanding.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

According to applicant product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* is intended only for professional and industrial users as a wood preservative in preventive treatment, outdoor, to be used in classes 3, 4 and 5[3]. The biocidal product family is the same as the active substance creosote and it is used against wood rotting fungi, wood rot in soil and water contact, insects and marine crustaceans and molluscs.

The product is intended mainly for treatment of timber by vacuum-pressure impregnation. Additionally applicant declared two non-pressure methods of application:

- treatment of wooden stakes/posts by a non-pressure method;
- brush treatment of wooden constructions.

These two last application methods had not been assessed in CAR – therefore applicant has submitted additional exposure scenarios.

2.6.2 Assessment of exposure to humans and the environment

Biocidal product family is the same as the active substance creosote, therefore active substance is the only substance of concern in biocidal product family *Olej kreozotowy*

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[3] Please note also that although different uses of creosote are considered in the assessment it does not mean that applicant has proved lack of appropriate alternatives for creosote for all of these uses (please refer to Annex 8).

gatunek B and Olej kreozotowy gatunek C. New exposure studies have been submitted for following scenarios concerning human health:

- treatment of wooden stakes/posts by a non-pressure method,
- re-installation of an old vineyard/renewal of posts and vines,
- brush treatment of wooden construction,
- biomonitoring in workers processing creosoted-wooden sleepers.

New studies concerning environmental risk have been submitted:

- tests on acute toxicity of creosote to invertebrates,
- analysis of losses of creosote from treated timber (transmission poles, railway sleepers, fences),
- adsorption/desorption test with leachates from sleepers.

Moreover risk for use creosote treated wooden stakes/posts in vineyards has been calculated.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The applicant Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o. is a member of Creosote Council Europe (CCE), Subgroup of Coal Chemicals Sector group CEFIC, therefore it has an access to information included in dossier for the active substance creosote.

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in CAR.

The threshold limits and labelling regarding human health risks listed in Annex 3: “Toxicology and metabolism – active substance” must be taken into consideration.

2.7.1.2 Toxicology of the substance(s) of concern

Creosote is a complex mixture of hundreds of distinct compounds, including bi- and polycyclic aromatic hydrocarbons, phenols, as well as heterocyclic, oxygen-, sulphur- and nitrogen-containing compounds. 106 compounds have been identified in the creosote under evaluation (see Table 1.1-2 in DOCII-A of the CAR).
Hence, the concept of substances of concern is not applicable in this case.

2.7.1.3 Toxicology of the biocidal product family

The toxicology of the biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* was examined appropriately according to standard requirements. Please note that the product family is the same as the active ingredient, no new toxicology studies for products were submitted. Therefore, the human health effects of the product family will be identical as described for the active substance in DocIII-A6 and DOCII-A of CAR.

2.7.1.3.1 Acute toxicity

Creosote has low acute toxicity when administered orally, dermally and via inhalation to rats – LD_{50} oral >3500 mg/kg, LD_{50} dermal >2000 mg/kg and LC_{50} inhalation >5000 mg/m^3 (aerosol).

Skin Irritation / corrosivity

Skin irritation can be considered to be the most critical acute/short-term effect, both as a result in the studies and in occupational practice. A critical non-irritant threshold dose for skin has not been established.

The product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* should be labelled with **Skin Irrit 2., H315 "Causes skin irritation".**

Eye Irritation / corrosivity

For eye irritation the effects in the eye irritation study were not significant. However, practical experience has shown that exposure to vapours arising from hot creosote has to be avoided due to their irritating nature for skin, eyes and the respiratory tract.

Skin sesnsitisation

In the sensitisation studies creosote proved to be sensitising in the Maximisation test (M&K test) and the product family *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* should therefore be labelled with **Skin Sens.1 H317 "May cause an allergic skin reaction"**.

2.7.1.3.2 Genotoxicity

The mutagenic potency of creosote was studied *in-vitro* in bacteria and mammalian cells and *in-vivo* test systems in rats and mice. The results show that the creosote types tested were mutagenic in 2 out of 4 *in-vitro* tests in the presence of a metabolising system (S9), while creosote was negative in the *in-vivo* test systems with respect to genotoxicity.

2.7.1.3.3 Long-term toxicity and carcinogenicity

Creosote produced a dose-dependent increase in the number of skin tumours, and gave rise to 3-5 times more tumours than expected based on their BaP content. Creosote is a complex mixture which contains several substances that are regarded as carcinogenic and mutagenic. The product family *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* should be labelled with **H350 ”May cause cancer”.**

Regarding other endpoints following long-term exposure, some parameters, apart from carcinogenesis, were investigated. None of these gave rise to significant findings. However, Carcinogenesis can be regarded as the most severe endpoint after long-term exposure.

2.7.1.3.4 Reproduction toxicity

In the teratology studies in rats there was an increase in post implantation loss (early resorptions) in the high dose group. The product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* should therefore be labelled with **Repr. 2 H361d “Suspected of damaging the unborn child”.**

In the two-generation reproduction study, a significant reduction in the number of live F1 offspring in the mid and high dose groups was observed.

The biocidal product family should therefore be labelled with **H360F ”May damage fertility”.**

A human health effects assessment of the product is also presented in DOCII-B of the CAR. The creosote types which are approved in EU according to the Inclusion Directive 2011/71/EU are creosote Grade B and Grade C as specified in European Standard EN 13991:2003. The creosote product family assessed in this PAR is conformative with Grade B and C. The basis for the health assessment of the biocidal product is further laid out in Annex 4: ”Toxicology – biocidal product.”

2.7.2 Exposure

2.7.2.1 Exposure of professional and industrial users

The exposure of professional and industrial users at impregnation plants and for down-stream users (pole installers) is extensively described and presented in DOCII-B and DOCII-C of the CAR. For the product family *Olej kreozotowy gatunek B and Olej kreozotowy* *gatunek C* applicant has submitted additional exposure scenarios in addition to those presented in the CAR.

These scenarios include:

- treatment of wooden stakes/posts by a non-pressure method;
- re-installation of an old vineyard/renewal of posts and vines;
- brush treatment of wooden constructions;
- biomonitoring in workers processing creosoted-wooden sleepers.

The additional exposure scenarios are summarised and evaluated in this Product Assessment Report. Details concerning exposure of professional and industrial users assessed in CAR are also described in section 2.7.3. and in Annex 5: "Safety for professional and industrial operators" to this PAR.

Wood preservation with the biocidal product family *Olej krezotowy gatunek B and Olej kreozotowy gatunek C* is restricted to professional and industrial users. Product family is the same as the active substance so the worker exposure studies that were evaluated by the SE RMS are considered to be appropriate for the product family *Olej krezotowy gatunek B and Olej kreozotowy gatunek C* assessment. The studies considered to be the most representative of European conditions are summarized in table 2.3.

Table 2.3 Summary of operator exposure at European impregnation plants assessed in CAR.

Study	No., sex of exposed persons, job	Measurements	Dermal*	Inhalation*
FIOH (2008): Creosote exposure at the Höljäkkä wood impregnation plant, Höljäkkä Oy. Finnish Institute of Occupational Health, 10 Jan. 2008	4, male / impregnation of poles, Standard PPE*	skin deposition (pyrene as marker substance),inhalation (PAH profile, 15 EPA prioritised PAHs),biomonitoring in urine: 1-OHP	Exposure: **40-57 µg/kg bw/day** (deposited *creosote* dose) Contaminations in general dominated by hand exposure.	Highest dose: 13 **µg/kg bw/day (without PPE)** (Σ15 PAH, with >60 % naphthalene)
van Rooij, et al. (1993) Effect of the reduction of	10, male / impregnation of railway ties; Standard and	skin deposition (pyrene as marker substance),inhalation (pyrene)biomonitoring	Exposure ranged from **63 µg/kg bw/day**	Range of **pyrene** 0.3-3 µg/m^3

skin contamination on the internal dose of creosote workers exposed to polycyclic aromatic hydrocarbons.	additional PPE*	in urine: 1-OHP	with additional protection to **210 µg/kg bw**/day without additional protection.	

*Inhalational exposure was measured outside the respiratory protection, and the presented figures was the for the maintenance operator who exhibited the highest exposure.

More details concerning the findings of studies FIOH, 2008 and van Rooij, et al. 1993, can be found inAnnex 5: "Safety for professional and industrial operators".

Evaluation

For the FIOH study, no whole-body skin exposure is available. The hand exposure values are in the same order of magnitude as in the van Rooij study. Overall, it can be assumed that the total body burden is of the same order. This is also suggested by the similarity of the urinary excretion data (see revised DOCIIIA-2.10).

Using the van Rooij study average skin contamination (without extra PPE) was 210 µg/kg bw/day, and with extra PPE 71.9 µg/kg bw/day. That means, the mean values are a factor of 5 (without extra protection) or of 15 (with extra protection). The FIOH displays a maximum average of 57 µg/kg bw/day which corresponds to a factor of 19. It is proposed that for risk calculation an average European factor is calculated. It should be based on the FIOH and the van Rooij study (with protective overall).

The average factor would be (71.9+57) µg/kg bw/day/2 = **64 µg creosote /kg bw/day**.

Exposure of down-stream users

A study on exposure of pole installers (Mäkelä et al. 2008) has also been evaluated in CAR. Work tasks were focused on installation operations on treated wooden poles for in-service preparation, such as furnishing and cutting of electricity poles, installation of conductors, and installation of a separator. The number of workers were 7 in total. The work also involved setting up poles, climbing of poles by using climbing irons, sawing and drilling.

Although the number of workers were quite few, the results anyway show that the exposure is, for most job tasks, at approximately the same level or lower as at the impregnation plants. Pole installers may also, during certain short job tasks, be exposed to wood dust containing creosote components. The study also showed that there are possibilities of considerable improvements of the risk reduction measures among down-stream users. Gloves were used for several days and were contaminated on the inside already at the beginning of the working day and tools and equipment may also have been contaminated with creosote already at the beginning of the working day.

More details concerning the findings of study Mäkelä et al. 2008, can be found in Annex 5: "Safety for professional and industrial operators".

<u>Estimation of whole-body exposure of pole installers to creosote</u>

The highest values for pyrene during the day are used and these are: A (Pole furnishing): 14.5 ng/cm^2, B (installation of conductors): 6.4 ng/cm^2, C (installation of a separator): 780 ng/cm^2.

By using the equation described in Table 2. in Annex 5 of this PAR an assumed whole-body exposure of creosote is obtained:

A: 26-37 µg/kg bw/day,

B: 11-17 µg/kg bw/day,

C: 1410-2000 µg/kg bw/day.

The lower values represent exposure when using light-weight chemical resistant overalls and the higher values represent exposure when using ordinary overalls. This is assumed to represent a situation equal to that in the exposure study by van Rooij (see DOCIII-2.10 and DOCII-B of the CAR), in where the use of an additional overall reduced the exposure considerably.

These exposure values are used in the risk characterisation.

<u>Additional exposure scenarios:</u>

Brush treatment of wooden constructions

Brush treatment is an application method that was not assessed in the CAR for creosote. Therefore applicant has submitted additional data supporting exposure during this process.

Modification of treated wood components may take place on the same site as in the industrial treatment process. This is typical for pole and sleeper production. In such cases up to 100 components may require exposed surfaces to be treated in one shift and these are handled in a defined area of the site on an impermeable surface. Enough creosote for up to 10 treatments at a time is drawn from a drum into a container into which a brush can be inserted, or the brush is loaded direct from a can with a wide opening.

Modification of treated wood components may also take place on a construction site. In such cases, creosote is applied by brush from a can with a wide opening. Treatment takes place on a bunded temporary impervious surface using a plastic membrane or pre-formed plastic tray.

Operation: in open, ventilated halls or open-air operation

Number of workers in total or per operation: typically 1 per shift

PPE: Oil-resistant PPE: coverall, apron, eye protection, shoes and elbow-length gauntlets

Duration of operation: 4-7 hours contact time

Amount of creosote used per shift: max. 5 litres

There are no measurements of exposure either in air or of the skin. Biomonitoring data neither is available.

Empirical data from related applications or model data are used to draw sufficiently robust conclusions about the order of magnitude of exposures arising from brush painting in comparison to known applications. It is understood that cut-end treatment is only a minor manual activity requiring a small amount of creosote.

Inhalation exposure

As the manual cut-end re-impregnation takes place at well ventilated sites, the foreseeable air concentrations are anticipated to be similar to those found outside elsewhere or lower than the low-end inside values. Gross model estimates appear to confirm this outcome (see Table 4. in Annex 5. of this PAR).

Dermal exposure

The internal body burden is mainly determined by the extent of skin contamination. Contact of the hands through contaminated gloves including wrists seems to be the major source rather than the remainder of the body surface. As a matter of fact, during most operations before or after impregnation manual operations are needed, resulting in more or less contaminated gloves.

Exposure of workers processing/machining creosote-treated wood

Applicant submitted new data concerning workers exposed to creosoted wood sleepers by skin contact or to dust and organic volatile compounds from creosoted wood sleepers by inhalation during machining or handling.

The exposure of workers was monitored in three ways:

1) atmospheric analytical monitoring of 16 PAHs as recommended by US EPA,
2) atmospheric analytical monitoring of wood dust,
3) biological monitoring of urinary metabolites in voluntary workers: 1-hydroxypyrene, 3-hydroxyB(a)P, 1-naphthol and 2-naphthol.

Considering the creosote composition characteristics, 16 PAHs were measured for atmospheric analytical monitoring of creosote. These PAHs are considered by US EPA and AFSSA (former name of ANSES) for risk assessment of PAHs mixtures (please see Table 6. in Annex 5 of this PAR).

Four different workplaces were considered:

- “poste A” – worker inside driving an automatic resizing chain of creosoted wood sleepers. Repeated exposure to dust and organic volatile compounds by inhalation and by skin contact can occur when the worker enters in the resizing room to clean the machine.
- “poste B” – worker at drilling station. Repeated skin contact and exposure to dust and organic volatile compounds by inhalation can occur.
- “poste C” – worker driving manual resizing for creosoted wood sleepers. Repeated skin contact and exposure to dust and organic volatile compounds by inhalation can occur.
- “poste D” – worker outside driving a conveyor belt providing creosoted wood sleepers. Repeated skin contact can occur as well as exposure by inhalation to organic volatile compounds.

Results:

PAH and cresosote wood dust concentration in air

Table 2.4 Concentrations of atmospheric PAHs and creosoted wood dust

Work -places	Naphthalene [µg/m^3]	B(a)P [ng/ m^3]	Sum of 16 PAHs based on AFSSA TEF [ng/ m^3]	Sum of 16 PAHs based on US EPA TEF [ng/ m^3]	Wood dust [mg/m^3]
A	23	1.35	130	11	0.93
B	9	1.8	57	18	0.27
C	62	7.7	282	103	4.01
D	8	1.67	54	8	-
VME	50 000	150	150	150	1

As we can see in table above, naphthalene and B(a)P atmospheric concentrations were always far lower than their respective threshold limit values, independent on the workplace.
For the workplaces, PAHs concentrations were expressed based on TEF of EPA and AFSSA.
For the workplaces with high PAH concentrations based on TEF of AFSSA, the corresponding PAH concentrations based on TEF of EPA were lower than 150 ng/m^3 B(a)P equivalency. Therefore, no important exposure to carcinogenic PAHs occurred, while creosoted wood machining led to exposure to “light” PAHs (two to four rings).
The two workplaces with high PAH concentrations based on AFSSA TEF corresponded also to the highest wood dust concentrations, as these dusts consist creosote.
Metabolite urine analysis
As some results for urinary metabolite concentrations were observed for the four workplaces, only urinary PAH excretion at one workplace was reported.
3-hydroxyB(a)P concentrations were low, in the same order as those observed by INRS in the general population. Therefore, there was no significant worker’s exposure to carcinogenic PAHs, for which 3-hydroxyB(a)P was the indicator.
1-hydroxypyrene concentrations in urine showed worker’s exposure to light PAHs, such as pyrene, which were not considered as carcinogenic.

During the week of work, 1-hydroxypyrene excretion slowly increased up to several hours after the end of the shift. This observation was in favour of skin absorption of pyrene. This hypothesis was corroborated by the highest 1-hydroxypyrene excretion after the second day when the worker wore contaminated work clothes of the week before.

However, excretion of naphthols was much faster than 1-hydroxypyrene excretion, showing that naphthalene was absorbed mainly by inhalation. Indeed, the highest concentration was observed at the end of the shift and decreased during the night.

Treatment of wooden stakes/posts by a non-pressure method and re-installation of an old vineyard/renewal of posts and vines;

Applicant submitted new data concerning impregnation of wooden stakes/posts by a hot-and-cold open tank (bath) method and installing them on the vineyard.

Impregnation process:

The immersion technique for wood preservation has minor importance as compared with the vacuum-pressure impregnation process, but it allows to impregnate only part of a wooden post which are preferentially employed in agriculture and horticulture.

The posts are placed upright into an open basket, while the bottom end is immersed in the treating tank containing creosote. The temperature-dependent process is conducted in a closed cabinet. Details are outlined in Addendum DOC-IIIA2.10.1/08.

The operations are not associated with any physical contact with the impregnated article and the preservative, most of the operations are accomplished by mechanical means like use of a crane, manual action is needed for removing the finished poles from the immersion basket and putting them into a metal cage for bundling and subsequent storage. Also this job can be carried out without contact to the treated end of the poles.

Operations are executed in open, well ventilated halls.

Number of workers in total or per operation: 1-2

PPE: compulsory protective clothing, working boots/shoes, and gloves

Duration of operations: 60-150 min.

Inhalation exposure

These measurements were part of a monitoring programme from 2005 to 2007, performed in various impregnation plants in Germany, two of them using the non-pressure impregnation process with creosote (BAuA project F 1809).

Site of impregnation and air sampling:

- plant M – during treatment, the tanks were located within a closed hall, whereas the immersion baskets were loaded with the posts and unloaded outside the hall.
- plant C - the impregnation tanks were located under a completely roofed working area that was open to three sides. The immersion baskets were loaded and unloaded under this roofing, while exhaust gases were directed through a scrubber facility.

Measurements (A):

1) performed for equivalent operations under similar conditions at both plants (results combined: see Table 2.5);
2) additional stationary monitoring at sites that were technically different.

Additional Measurements (B)

- plant M – stationary in the closed hall during impregnation without people present (with maximum tar-oil temperature of 110-120°C).
- plant C – stationary by the temperature display during loading, treatment and unloading in intervals of about 1 h, while recording the temperature profile.

Results (A):

Table 2.5 Monitoring data of the sum of PAHs during equivalent operations of loading and unloading in plant M and C (Hebisch et al. 2009, Tab. 6.11)

Type of measurement	Number of measurements	Range of exposure [mg/m³]	Median [mg/m³]	95-Percentile [mg/m³]
all	17	0.12-3.3	0.36	2.4
stationary	9	0.12-3.3	0.15	-
personal	8	0.24-2.1	0.46	-

The highest values, either stationary or personal, were measured in the plant with the treatment tanks in a closed hall (plant M). The loading and unloading operations, but also the measurements of the tar-oil level resulted in short-term peaks of exposure.

Results (B):

- plant M – the concentration levels of PAH were 10-12 mg/m^3.
- plant C – the maximum PAH level (of 3 test series) was 6.5 mg/m^3 at the maximum temperature of 120°C. After the first (loading, T = ~75°C) and the final interval

(unloading, T = ~100°C), the PAH levels accounted for about 25 to 50% of the maximum.

PAH Profile: Detailed analyses of individual components have not been provided for this impregnation process.

Detailed results of the monitoring study can be found in Addendum DOC-III.A2.10.1/08.

Dermal exposure:

No specific monitoring data about skin contamination during wood impregnation using the hot-and-cold impregnation process has been located. Likewise, biomonitoring data – as indicator of internal body burden – is not available for this process.

On the other hand, the external contamination of the working clothes has been investigated in three pressure treatment plants (plants A, B, D) and in one plant using the hot-and-cold immersion process (plant C). Addendum DOC-III.A2.10.1./08 contains the contamination data for operations related to the pressure process. For plants A, B and D also biomonitoring data are available.

Re-installation of an old vineyard / renewal of posts and vines / establishing as trellis system

This task usually is performed in two stages:

1) Removal of the old posts: Supporting wires are removed manually, posts are withdrawn mechanically, collected and loaded on a trailor, usually manually and transported to a certified waste disposal contractor for eventual combustion in a power plant for hazardous wastes.
2) Setting-up of new posts: New post are transported on a trailor to the field, and portions are deposited at several rows. The posts are planted mechanically using heavy equipment for driving the post ends into the soil (pile-driving machine). About 25 cm of the impregnated part of the posts have to remain above ground. After post-driving, mounting and fitting components and the bracing wires are to be installed.

This task is performed wearing a PPE – protective clothes and gloves. Overall, in general no contact with creosoted zone of the wood is expected.

Inhalation exposure

No monitoring data are available, but considered to be negligible, because posts going to be in service have been aged/weathered for a time. The job is done at open air.

Dermal exposure

No monitoring data are available, but dermal exposure is considered to be negligible, because posts going to be in service have been aged/weathered for a time, and wearing of protective equipment is obligatory. Furthermore, skin contact can easily be avoided by adequate handling of the articles, since only the bottom ends of the posts have been treated with creosote.

2.7.2.2 Exposure of non-professional users and the general public

Exposure of the general public is considered not to be relevant since creosote is only to be used by professionals and industrial users. Furthermore, exposure has been shown to be clearly connected to the proximity to the treating cylinder. Margin of Exposures (MOEs) for workers are far above 25000 (often several 100000, see DOCII-C of the CAR) and any occasional exposure by the public by for example touching a pole would lead to even much larger MOEs.

Inhalational exposure at the impregnation plants account for a small part of the total exposure levels. Investigations regarding emissions to ambient air at two American pressure treatments plants have shown the ambient air emissions for naphthalene, which is the most significant PAH air emission, are close to background concentrations. Other, more high-molecular weight PAHs are below detection levels. Consequently, there is no apparent elevation in health risks for people living nearby creosote treatment plants.

In contrast, odour can be problematic in the vicinity of creosote treatment plants. It has to be stressed that odour per se does not necessarily pose a health risk.

Smell around creosote impregnation plants has been known since long. This problem can be overcome, and is therefore more of a problem for individual plants.

The smell is confined to three major activities at the plants:

1. From the air from the vacuum pump during the process.
2. When opening of the cylinder door when hot newly treated timber is exposed to cold air.
3. During storage of timber in the yard.

Item 1 is/can be solved by feeding the air from the vacuum pump to an incinerator.

Item 2 is/can normally be solved by extracting the hot air from the cylinders until the wood has cooled down, and the air should, as in point 1, then be the subject of incineration.

Item 3 is coupled to usage of creosote oils with high amount of light boiling components such as naphthalene, which volatilise more easily. High amounts of light boiling components are in many cases coupled to low technical standards of the plants. Creosote oils with higher boiling points do not cause these problems.

In summary, a well-technically upgraded creosote plant in which the air emissions are incinerated coupled with usage of well-engineered creosote oils will cause minimal problems for the neighbourhood.

2.7.2.3 Exposure to residues in food

Wood treated with creosote is not to be used in the vicinity of food or feed. Hence, residues are not anticipated. However, uses such as fruit tree stakes and vine stakes may pose questions if residues are possible. For vine stakes, only the lower 1/3 of the stakes are treated with creosote, i.e., the part of the stake in contact with the ground. The applicant has commissioned a study aiming at investigating the matter of potential residues. That study is not finalised.

2.7.3 Risk Characterisation

Generally, for biocides, the risk characterisation is performed by a comparison of the exposure with the AOEL and also by the MOE (Margin of Exposure) approach (for calculation of MOEs the exposure is usually directly compared to a relevant NOAEL by dividing the NOAEL with the exposure value). However, as stated in DOCII-A of the CAR for creosote, point 3.13, an AOEL cannot be set for creosote, since creosote is classified as Carc.1B; H350, ”May cause cancer” (Cat 2), and is considered to be a complete carcinogen, i.e., with both initiating and promoting capacity with respect to tumour formation. There is theoretically no safe exposure level for non-threshold carcinogens. Hence, a risk characterisation for creosote by comparison of the exposure in relation to an AOEL cannot be performed.

In cases where a NOAEL cannot be identified (i.e., for genotoxic and non-threshold carcinogenic substances), the MOE can instead be calculated by comparing the exposure with other reference points such as the dose descriptor T25.

The dose descriptor T25 gives an indication of the dose of a chemical resulting in a fixed incidence of tumours (in this case 25%). The T25 approach has been used for creosote by other bodies (Scientific Committee for Toxicity, Ecotoxicity and the Environment, CSTEE) and for non-threshold carcinogens by the Scientific Committee on Consumer products (SCCP), and also by EFSA. It has also been used for other substances within the EU, and it was used also in the CAR for creosote.

For substances regarded as non-threshold carcinogens a qualitative risk characterisation is always performed as a first option. Creosote is already stringently regulated as laid down in the "Marketing and Use Directive" 2001/90/EC, and further risk reduction measures are suggested at the end of this chapter. A quantitative risk characterisation may be performed on a case by case basis and such a risk characterisation is presented for creosote in DOCII-C of the CAR. Guidance can be found in the *TNsG for Annex 1 inclusion*, in the revised and endorsed chapter 4.1, in ECHA (2008): *Guidance on information requirements and chemical safety assessment*, Chapter R.8, and in the *Report: Risk assessment methodologies and approaches for mutagenic and carcinogenic substances* (SCHER, SCCP, and SCENIR, 2008).

For further details, please refer to DOCII-C of the CAR.

Table 2.6 Summary of relevant exposure paths for humans

Exposure path	Professional and industrial use	General public	Via the environment
Inhalation	Yes	Of minor importance	Of minor importance
Dermal	Yes	Of minor importance	Of minor importance
Oral	Negligible	Negligible	Negligible

2.7.3.1 Risk for Professional and Industrial Users

Table 2.7 Exposure of operators to creosote

Exposure scenario	PPE	Dermal uptake	Inhalational uptake
Impregnation of poles and railway ties. All scenarios Down-stream users (pole installers) For more details see DOCII-B, 8.2 of CAR and Annex 5 of this PAR	Varying (see Table 1 in Annex 5 of this PAR)	Average doses: **64 µg/kg bw/day,** with PPE (deposited *creosote* dose) Specific exposure for different categories of workers are presented in Table 2 of Annex 5 of this PAR	Sum of detectable PAHs: **13 µg/kg bw/day**, without PPE, and **0.13 µg /kg bw/day**, with PPE (Σ15 PAH, with >60% naphthalene)

The product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* is identical as the active substance. No new data concerning dermal absorption of product family was provided so dermal absorption value from CAR was used.

For dermal absorption a value of 10% is used as agreed at TMII-2008 and TMIV-2008, and it was also decided that calculations using 5% should be presented as well. For inhalational uptake a value of 100% is used.

For more details regarding dermal absorption, please see point 2.1 in the DOC II-B of the CAR for creosote.

In the risk characterisation two different MOE are presented for some of the toxicity endpoints. One MOE in which the major route of exposure (dermal) is taken into account and one MOE in where the inhalational exposure (with PPE) is included. However, it has to be understood that the toxicological profile for the volatile fraction of creosote is completely different from that of whole creosote to which animals are exposed orally or dermally and to which workers are exposed dermally, and hence, it can be questioned if the volatile fraction really should be included. Moreover, the workers use respiratory protection at critical work tasks. The volatile fraction consists of a few detectable light-boiling PAHs with naphthalene as a major component (60->90%). More toxic and carcinogenic PAHs (e.g., BaP) seem not to volatilize.

Table 2.8 Summary of the potential creosote exposure to operators with respect to different time frames and toxicity endpoints

	NOAEL	Exposure	MOE [1), 2)]
Subchronic dermal toxicity test	400 mg/kg bw/day	3.2 µg/kg bw/day (64 µg/kg bw/day x **5%** dermal absorption)	**MOE = 125000**
		6.4 µg/kg bw/day (64 µg/kg bw/day x **10%** dermal absorption)	**MOE = 62500**
		13.6 µg/kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 29411**
Subchronic inhalation toxicity test	22 mg/m^3 corresponds to 5.5 mg/kg bw per rat[3)]	Sum of detectable PAHs: 0.13 µg/kg bw/day (with PPE) (Σ15 PAH, with >60 % naphthalene)	**MOE = 42307**
Teratogenicity test (rat, rabbit: oral)	50 mg/kg bw/day (rat)	Dermal exposure 3.2 µg/kg bw/day (64 µg/kg bw/day x **5%** dermal absorption) Dermal exposure 3.2 µg/kg bw/day + inhalational exposure 0.13 µg/kg bw/day (Sum of detectable PAHs: (Σ15 PAH, with >60% naphthalene) = 3.33 µg/kg bw/day	**MOE = 15625** (rat NOAEL oral vs. dermal bioavailability to be considered) MOE (inhalation included) = 15015
		Dermal exposure 6.4 µg/kg bw/day (64 µg/kg bw/day x **10%** dermal absorption) Dermal exposure 6.4 µg/kg bw/day + inhalational exposure 0.13 µg/kg bw/day (Sum of	**MOE = 7812** (rat NOAEL oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1)] = 7657

		detectable PAHs: (Σ15 PAH, with >60 % naphthalene) = 6.53 µg/kg bw/day	
			MOE = 3676
	9 mg/kg bw/day (rabbit)	13.6 µg/kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE (rabbit) = 1406** (rabbit NOAEL oral vs. dermal bioavailability to be considered) MOE (rabbit, inhalation included)[1)] = 1378
Two generations reproduction study	25 mg/kg bw/day	Dermal exposure 3.2 µg/kg bw/day (64 µg/kg bw/day x **5%** dermal absorption) Dermal exposure 3.2 µg/kg bw/day + inhalational exposure 0.13 µg/kg bw/day (Sum of detectable PAHs: (Σ15 PAH, with >60% naphthalene) = 3.33 µg/kg bw/day	**MOE = 7812** (rat NOAEL oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1)] = 7507
		Dermal exposure 6.4 µg/kg bw/day (64 µg/kg bw/day x **10%** dermal absorption) Dermal exposure 6.4 µg/kg bw/day + inhalational exposure 0.13 µg/kg bw/day (Sum of detectable PAHs: (Σ 15 PAH, with >60% naphthalene) = 6.53 µg/kg bw/day	**MOE = 3906** (rat NOAEL oral vs. dermal bioavailability to be considered) MOE (inhalation included)[1)] = 3828
		13.6 µg/kg bw/day (highest value from the FIOH study, **10%** dermal absorption)	**MOE = 1838**

[1)] Abbreviations: MOE = Margin of Exposure (NOAEL/Exp.) Generally a MOE of >100 is considered to be adequate. Moreover, an additional factor of 10 should be used, since creosote is classified as Canc. Cat 2. This results in a factor of 1000, i.e., the MOEs should preferably be 1000.
[2)] The use of respiratory protection has been taken into account when inhalational exposure has been included.

3) The dose (mg/kg bw) received by the rats in the 90-day study

NOAEL = 22 mg/m^3= 0.022 mg/L
Rat breathing rate = 175 ml/min = 10.5 L/h = 63 L/day (6 h in this study)
Rat weight = 250 g
Dose received at NOAEL = 0.022 mg/L x 63 L/day /0.25 kg = 5.5 mg/kg bw/day

All MOEs can be considered to be acceptable.

For more details please refer to DOC.II-C of the CAR for creosote.

Risk characterisation of different working scenarios with respect to cancer risk

In the revised cancer risk characterisation the revised dermal absorption value of 5% and the highest exposure values from the European plants are used (see DOCII-B of the CAR for creosote). At TMII-2008 it was decided that 10% dermal absorption shall be used, and that figures obtained using 5% dermal absorption shall be presented as well.

For systemic cancers, it is clear that 10% (or 5%) dermal absorption should be used. Even for skin cancer this may very well be the case since several of the components need to penetrate the skin in order to be metabolised and thereby exhibit any potential carcinogenic properties. In any case, the substances need to penetrate into the cells in order to be genotoxic.

A risk characterisation of the working scenarios with respect to cancer risk can be performed by calculating the MOE by using the T25 value.

The following corrected T25 is obtained and used in the risk characterisation:

CorrT25 = 1690 mg/kg bw/day

Detailed description of derivation of corrected T25 value can be found in the DOCII-C of the CAR.

The resulting MOEs are presented in the table below. **It should be noted that the MOEs should preferably be 25 000 (in addition of the conventional 10 x 10, an additional factor of 10 should be used, since creosote is classified as Carc. Cat 2, and an extra additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL. An extra factor of 2.5 is used for the fact that the T25 value represents a 25% level of the number of tumors. A MOE of 25000 is obtained if an inter individual factor of 10 (i.e., not a factor of 5 for workers) is used in combination with the extra factor of 2.5.**

Table 2.9 Summary of the creosote exposure to operators with respect to different exposure scenarios and cancer risk using 5% and 10% dermal absorption for comparison as decided at TMII2008

Exposure scenario [1)]	Potential exposure	
	µg/kg bw/day [2)]	MOE [3), 4)]
Management Operator (MO, who exhibited the highest exposure in the FIOH study.) Changed the creosote buggy wheels and replaced a creosote cylinder door gasket.	Dermal: 6.8 (**5%** dermal absorption used)	**248529**
	13.6 (**10%** dermal absorption used)	**124264**
Worker (WO, who exhibited the second highest exposure value next to the MO in the FIOH study) Unloading/loading and charging of the cylinders, repair	Dermal: 2.8 (**5%** dermal absorption used)	**603571**

and maintenance. Load changes included the removal of processed pole buggies from the impregnation/after-treatment cylinder (unloading) and the charging of new buggies into the cylinder (charging). The change took approx. 15-30 minutes, of which a few minutes were spent in the vicinity of the impregnation/after-treatment cylinder.	5.6 (**10%** dermal absorption used)	**301786**
Worker (WO, who exhibited the highest exposure value in the van Rooij study). Controlling the process, transport of the wood into and out of the cylinder on rail trucks, opening and closing if the covers of the cylinder.	Dermal: 9.5 (**5%** dermal absorption used)	**177895**
	19 (**10%** dermal absorption used)	**88947**
Worker. Average exposure at impregnation plants for the two studies (64 µg/kg bw/day)	Dermal: 3.2 (**5%** dermal absorption used)	**528125**
	6.4 (**10%** dermal absorption used)	**264062**
Down-stream users (pole installers)		
Pole installers. Furnishing of poles. With the use of light chemical resistant overall	Dermal: 1.3 (**5%** dermal absorption used)	**1300000**
	2.6 (**10%** dermal absorption used)	**650000**
Pole installers. Furnishing of poles. Without the use of light chemical resistant overall	Dermal: 1.8 (**5%** dermal absorption used)	**938888**
	3.7 (**10%** dermal absorption used)	**456756**
Pole installers. Installation of conductors. With the use of light chemical resistant overall	Dermal: 0.56 (**5%** dermal absorption used)	**3017857**
	1.1 (**10%** dermal absorption used)	**1536363**
Pole installers. Installation of conductors. Without the use of light chemical resistant overall	Dermal: 0.85 (**5%** dermal absorption used)	**1988235**
	1.7 (**10%** dermal absorption used)	**994117**

Pole installers. Installation of a separator. With the use of light chemical resistant overall	Dermal: 70.5 (**5%** dermal absorption used)	**23971**
	141 (**10%** dermal absorption used)	**11985**
Pole installers. Installation of a separator. Without the use of light chemical resistant overall	Dermal: 100 (**5%** dermal absorption used)	**16900**
	200 (**10%** dermal absorption used)	**8450**

[1)] It has to be noticed that a distinction between different job categories and scenarios is difficult to make, since many of the workers perform several job categories. For pole installers the use of and non-use of a light chemical resistant overall, respectively, is assumed to represent a situation equal to that in the exposure study by van Rooij (see DOC2.10 and DOCII-B of CAR), in where the use of an additional overall reduced the exposure considerably.

[2)] The exposure values are obtained from the study reports (FIOH 2008a, Mäkelä 2008 and Van Rooij 1993), see new study summaries in revised DOCIII-A2.10, point A2.10.1, and revised DOCII-B of the CAR, and the systemic exposure is obtained by accounting for 5% and 10% dermal absorption. Please note that the highest exposure values have been used. Furthermore, at TMII-2008 it was decided that 10% dermal absorption shall be used, and that values for 5% should be presented as well for comparison.

[3)] The inhalation exposure is not included since only a few PAHs were detectable in the volatile fraction and naphthalene accounted for >60%. The large molecular weight PAHs (and most toxic and carcinogenic, e.g., BaP) were not detected, presumably due to low volatility. The toxicological profile for the volatile fraction of creosote is completely different from that of whole creosote to which animals are exposed orally or dermally and to which workers are exposed dermally, and hence, the volatile fraction was therefore not included. Moreover, the workers wear respiratory protection at critical work tasks.

[4]) The exposure to creosote can be considered to be chronic, since the workers can be exposed every working day for the entire working life. The MOEs have been calculated by comparing the exposure with the T25 value (corresponds to a dose of BaP in creosote resulting in a 25% increased incidence of tumours over a life span) (identified by CSTEE, 1999) of 13 BaP μg/kg bw/day, corresponding to 1300 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). This is corrected by a factor of 5, since the creosote types were 5 times more potent than the control based on BaP content, resulting in 260 mg/kg bw/day creosote (assuming a BaP content of 10 ppm). The T25 value is also corrected to account for differences in exposure conditions in order to obtain a corrected T25 or human T25. The corrected T25 is 1690 mg/kg bw/day (see text above the Table). The MOEs should preferably be 10000 (an additional factor of 10 should be used, since creosote is classified as Canc. Cat 2, and an additional factor of 10 should be used when an effect dose, i.e., T25 is used and not a non-effect dose, i.e., a NOAEL). Please see CAR for more details.

Derived Minimal Effect Level (DMEL)

The derivation of a Derived Minimal Effect Level (DMEL) is described in ECHA (2008): *Guidance on information requirements and chemical safety assessment*, Chapter R.8). It should be pointed out that, although there is theoretically no safe exposure level for non-threshold carcinogens, the DMEL obtained represents a risk level that is considered to be of very low concern.

Detailed description of derivation of DMEL value can be found in the DOCII-C of the CAR.

DMEL = 68 µg/kg bw/day

It is concluded that there are sufficient MOEs at the European impregnation plants, and that the exposure levels are below a DMEL that represents a risk level, that according to available guidance, is of low concern (10^{-5}).

Acceptable uses are identified as far as acceptable uses can be said to exist for a genotoxic carcinogen.

The only exception is for pole installers during a special time-consuming work task of installing a separator. Strict risk reduction measures are to be applied. PPE was used in an inadequate way. Gloves were, for example contaminated already before the work shift. Proper use of PPE will reduce the exposure considerably. It can also be noted that this kind of work is not performed every day all year around.

Brush treatment

As mentioned in section 2.5.1., brush treatment of wooden constructions is only a complementary method to treat wood in its final form after all cutting, shaping and machining has been carried out so that the protective envelope of preservative is not broken.

It is possible the duration of operation is longer than in the exposure scenarios used in DOC-IIB, 8.2.2 of CAR for creosote. In addition, the operations during brushing of wooden constructions are performed in an open process. Hence, it cannot automatically be anticipated that the exposure levels are lower than those assessed in CAR.

The degree of dermal contamination and/or urinary excretion of 1-hydroxypyrene during cut-end treatment has not been measured or estimated. There is potential for direct physical contact with the impregnated articles or preservative draining from the brush. This potential is anticipated to be significantly less than that arising from direct and intense contacts during those operations addressed in CAR.

It is reasonable to assume that the exposure following brush application is lower than those described for other work tasks.

Exposure of workers processing/machining creosote-treated wood

The results of the monitoring programme presented in this study are compared with the results presented in the CAR in order to obtain information if exposure following the work tasks presented here is in approximately the same magnitude as the exposure levels at pressure impregnation plants presented in the CAR.

In order to obtain a view regarding if the exposure is comparable to the exposure level and risk characterisation presented in the CAR the inhalational exposure and bio-monitoring (1-OHP in urine) data is compared with the exposure levels presented in the CAR.

The inhalational exposure is approximately at the same level as in the studies presented in the CAR, and are below existing threshold limits.

The results of 1-OHP in urine (µmol/g Creatinine) in the present study is up to µmol/g creatinine for the worker with the highest exposure. This equals 82 nmol/L, if assuming an average content of 1 g creatininie per 1 liter of urine (MW of 1-OHP is 218 g/mol). In the studies in the CAR the levels were: up to 43 nmol/L in the FIOH study (2008) and 38.8 and 16 nmol/L, (without and with additional coverall, respectively) in the Van Rooij study (1993). Please note that the measured levels in the present study were after three working days, while the measurements in the studies in the CAR (FIOH and Van Rooij) were after one work shift. Further uncertainties in the comparison of exposure levels is the assumption of an average creatinine content in urine of 1 g/L (according to ACGIH).

Nevertheless, the present study show that for most work tasks, the exposure levels seem to be approximately as the levels presented in the CAR. However, at the same time the present results show that the exposure levels need to be decreased. More stringent adherence to the protective measures used at the work place and described in the CAR is needed.

Furthermore, as outlined in Directive 2011/71/EU (inclusion Directive) “it is appropriate to require that product authorisations for biocidal products containing the substance are subject to the requirement that all possible measures in accordance with Regulation (EC No 1907/2006 and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (5) be applied to protect workers, including down-stream users, from exposure during treatment and handling of treated wood.”

Impregnation of wooden stakes/posts by a non pressure method:

The results of the monitoring programme presented for this application method are compared with the results presented in the CAR in order to obtain information if exposure following the work tasks presented here is in approximately the same magnitude as the exposure levels at pressure impregnation plants presented in the CAR. In order to obtain a view regarding if dermal exposure is comparable to the exposure level and risk characterisation presented in the CAR, the procedure is not straightforward, since bio-monitoring (1-OHP in urine) data is not available for the non-pressure work tasks (hot-and-cold impregnation).

However, a comparison of the external contamination of the working clothes between the non-pressure treatment plan (Plant C) and the pressure treatment plants (A, B and D) can be made and subsequently, the bio-monitoring data which is available for plants A, B and D can be compared with the data in the CAR. A pre-requisite for this procedure is that the contamination level at plant C is in the same order or lower as in the plants A, B and D.

The exposure levels (measured as contamination of working clothes) at plant C seem to be in the same magnitude as in plants A, B and D. Hence, this allows a comparison of the bio-monitoring results at the pressure treatment plants with the results presented in the CAR. The results of 1-OHP in urine (µg/g Creatinine) in the present study is in the range of 2.2 – 105 µg/g creatinine for high exposure work tasks. The medians for these works tasks were: 5.1, 39.9 and 53.5 µg/g. This equals 10-482 nmol/L and 23.4, 183 and 245 nmol/L, for the range and different medians, respectively, if assuming an average content of 1 g creatinine per 1 liter of urine (MW of 1-OHP is 218 g/mol). In the studies in the CAR the levels were: up to 43 nmol/L in the FIOH study (2008) and 38.8 and 16 nmol/L, (without and with additional coverall, respectively) in the Van Rooij study (1993). Please note that the measured levels in the present study were after three working days, while the measurements in the studies in the CAR (FIOH and Van Rooij) were after one work shift. Further uncertainty in the comparison of exposure levels is the assumption of an average creatinine content in urine of 1 g/L (according to ACGIH).

Nevertheless, the present study show that for most work tasks, the exposure levels seem to be approximately as the levels presented in the CAR. However, at the same time the present results show that the exposure levels need to be decreased.

Furthermore, as outlined in Directive 2011/71/EU (inclusion Directive) “it is appropriate to require that product authorisations for biocidal products containing the substance are subject to the requirement that all possible measures in accordance with Regulation (EC) No 1907/2006 and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (5) be applied to protect workers, including down-stream users, from exposure during treatment and handling of treated wood.”

Treatment of wooden stakes/posts by a non-pressure method and re-installation of an old vineyard/renewal of posts and vines.

For work with re-installation of an old vineyard/renewal of posts and vines/establishing as trellis system, it is reasonable assume the exposure levels are lower than those that were described in the CAR.

Re-installation of an old vineyard/renewal of posts and vines may raise question regarding possible residues in grapes and fruit. Although it is unlikely that significant amounts of residues would appear in grapes and fruit, the applicant has commissioned a study to address the question of possible residues. This study is not finalised.

Based on the risk characterisation presented in the DOCII-C of the CAR and its comparison with the estimated exposure levels in the additional work scenarios presented in this product assessment report, a risk for professional and industrial users resulting from the intended uses is not expected when personal protective equipment (gloves and coverall) are worn. It was concluded in the CAR that there are sufficient Margin of Exposures (MOEs) at the European impregnation plants, and that the exposure levels are below a Derived Minimal Effect Level (DMEL), which represents a risk level, that according to available guidance, is of low concern (10^{-5}).

In the CAR, acceptable uses were identified as far as acceptable uses can be said to exist for a genotoxic carcinogen.

In the additional work tasks presented for this application, the exposure levels seem to be approximately in the same range as the levels presented in the DOCII-B and DOCII-C of the CAR. Hence, the MOEs and exposure levels which are below the DMEL in the CAR can be said to be applicable and valid also for the additional exposure scenarios. However, at the same time the present results show that the exposure levels need to be decreased. More stringent adherence to the protective measures used at the work place and described in the CAR is needed. Furthermore, the conditions, restrictions and requirements to be followed are described in the Inclusion Directive 2011/71/EU.

Furthermore, it is estimated that the exposure situation can be further improved by extra protective measures during work tasks where there is a risk of exposure. Protective measures not mentioned below can also be of importance and hence be applied as well:

- Stringent adherence of the protecting measures that are already in place.
- The PPE should be changed frequently, and immediately after contamination. Inhalational PPE shall be changed at required intervals.
- The personal hygiene shall be strict, and washing with suitable cleaning solutions shall be performed as soon as possible after each work task where there is a risk of exposure.

Risk of exposure means direct skin contact or inhalation of the vapors. However, risks vary depending on the construction of the plant and during non-routine activities. Risks can, for example, occur when opening and maintaining of the vessel or entry into treating or preservative storage vessels. In these cases, additional protection can be advised:

- Respiratory protection, such as a full face mask with particle filter P2 or preferably P3 in combination with gas filter A (brown) should be worn at critical work tasks when there is a risk of inhalation exposure.
- Chemical resistant (coated) coveralls, or equivalent, should be worn over the regular work clothes at critical work tasks when there is a risk of exposure, and a thinner pair of (cotton) gloves should be worn under the chemical resistant gloves.
- Whenever possible, mechanical or automated processes should be used to avoid manual handling of treated timber (including down-stream work, for example during work with poles in service).
- Creosote-resistant boots should be worn when entering the vessel (e.g. for cleaning or maintenance).
- In order to ensure efficient protection, tight sealings (sleeve capes) may be used at the border of different garments, e.g., at the border of gloves and sleeves and at the border of trousers and boots.

In addition:

- The working areas such as the treatment/equalization hall shall be cleaned when judged necessary based on monitoring or inspections. Other areas such as changing and washing rooms, break rooms and control rooms shall be cleaned weekly. Relevant equipment and tools shall be cleaned in case of contamination.
- Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.

In addition, further risk reduction measures could be the following simple solutions that may reduce the exposure of pole installer substantially:

- Strict adherence to proper working conditions.
- Increased use of aerial access platforms (exposure is clearly connected to close contact with the poles).
- Hand and face wash possibilities in the field.
- Use of light chemical resistant coveralls.
- Use of dry poles (wet poles can be returned to the impregnation plants, and use of sectorially impregnated poles, the poles may be more impregnated at the bottom regions that are in contact with the ground and less impregnated at regions that are above the ground).

2.7.3.2 Risk for non-professional users and the general public

The product family is intended only for professional and industrial users.

2.7.3.3 Risk for consumers via residues

Wood treated with creosote is not to be used in the vicinity of food or feed. Hence, residues are not anticipated. However, uses such as fruit tree stakes and vine stakes may pose questions if residues are possible. For vine stakes, only the lower 1/3 of the stakes are treated with creosote, i.e., the part of the stake in contact with the ground. The applicant has commissioned a study aiming at investigating the matter of potential residues. That study is not finalised.

2.8 Risk assessment for the environment

2.8.1 Effect, fate and behaviour assessment

The biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* is intended to be used as wood preservative as it is, i.e. the active substance – creosote is the product and there is no formulated product family. Therefore all data on creosote are directly applicable in assessment of biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* .

According to guideline if new data/information on the ecotoxicity or fate and behaviour has been submitted for the product or for the active substance(s) compared to the CAR it should be assessed and the results of the assessment are summarised here.

Applicant has submitted two new tests on acute toxicity of creosote to invertebrates.

Table 2.10 Acute toxicity to invertebrates – new data

Test subst.	Guideline/ Test method	Spp.	Exposure		Results			Remarks/ Reliability	Reference
			design	duration	EC_0 [mg/L]	EC_{50} [mg/L]	EC_{90} [mg/L]		
Wash oil	OECD 202	*Daphnia magna*	static	48 hours	1	2.74	3.2	results based on nominal concentration GLP reliability 3	Doc IIIA 7.4.1.2/6
Anthracene oil	OECD 202	*Daphnia magna*	static	48 hours	5	22.4	100	results based on nominal concentration GLP reliability 3	Doc IIIA 7.4.1.2/7

According to the laboratory the study is performed in accordance with principles of Good Laboratory Practice and the study is considered to be fairly acceptable.

The results are based on nominal concentrations as there are no measurements performed of the actual concentrations and the concentrations of the Total Organic Carbon (TOC) analysed deviate more than 20% throughout the test. The lack of measured concentrations and/or available evidence to demonstrate that initial concentrations have been maintained is found to be a deviation from the OECD 202 guideline and the results are considered uncertain.

Moreover tested substances are not fully representative for creosote fraction B and C. Studies are acceptable as additional information. Results of these tests do not invalidate and do not replace result of key study used in CAR for creosote to set $PNEC_{water.}$ It should be pointed that according to CAR the most sensitive species among water invertebrates is *Mysidopsis bahia* with LC_{50} of 0.018 mg/L. Result of this test indicates clearly that new data submitted for the product authorisation on *Daphnia magna* does not represent the most sensitive species. Summary and evaluation of effect data and fate and behaviour for the active substance can be found in Competent Authority Report for creosote prepared by SE. Data submitted by Applicant does not provide information which can influence on mentioned evaluation of effect and fate. Therefore list of endpoints for active substance creosote can be used in evaluation of effect caused by biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C*.

In the Assessment Report for creosote in point - requirement for further information it is stated: "The following data gaps were identified: Validation data for a monitoring method for soil and data on route of degradation in soil and the extent and nature of bound residues". This information should be submitted as part of applications for product authorisation. The data submitted by Applicant concerning the route of degradation and possible toxic metabolites are considered to be sufficient for the present product authorisation application. However, for an application of renewal of the active substance approval, a more thorough inspection of the data is needed.

2.8.2 Exposure assessment

The environmental exposure assessment of biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* has been performed following the general guidance in the OECD's emission scenario document (ESD) for wood preservatives (OECD, 2013) and the *Technical Guidance Document on Risk Assessment* (TGD), Part II (EC, 2003).

Biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* is used as wood preservative as it is, i.e. the active substance is the product family and there are no other components. It is used only in industrial preventative treatment of wood. According to applicant treated wood is used in the following use classes:

Use class 3: wood not covered and not in contact with the ground but continually exposed to weather or, protected from weather but subject to frequent wetting (e.g. fence, house, noise or snow barrier and railway sleepers),

Use class 4a: wood in contact with the ground (e.g. transmission pole, fence post, post in agriculture),

Use class 4b: wood in contact with freshwater (e.g. jetty in a lake, sheet piling in waterway),

Use class 5: wood permanently exposed to sea water, i.e. salt water (e.g. harbour wharf).

The ESD for wood preservatives (2013) does not specify the use class belonging of railway sleepers. But since this use area for biocidal product is very extensive the use class belonging needed to be identified in order to be able to properly assess the risk from this use. SE has suggested that the use class belonging should be use class 3 since the sleepers are always placed on a bed of ballast (e.g. crushed stone) which can be regarded as a fairly inert material which cannot be considered to have the same „extracting" capacity as soil or water. Further, the creosote components leached out from the wood will first end up in, or rather on, the ballast where they will be much more exposed to abiotic degradation and volatilisation than creosote components leached out into, or onto, soil. At TMII08 it was also agreed that the railway sleepers should be considered to belong to use class 3. In the new ESD for wood preservatives (2013) railway sleepers are considered in use class 3 and emission scenario for this use was proposed.

The ESD for wood preservatives (2013) does not propose the emission scenario for post in agriculture (vineyards, orchards). Because of similarities to transmission poles the same approach was used to calculate emission from post used in agriculture.

The exposure assessment of biocidal product includes the estimation of local emissions to various receiving environmental compartments from only two stages of the life cycle, i.e. industrial product application and treated wood in-service. This implies that other life cycle stages like production, waste treatment, etc. are not covered by the following assessment. This is considered to be covered by other pieces of legislation.

Emission rates from wood treated with creosote

The intended use of creosote is for treatment of wood to a retention of 40-150 kg/m^3. At a very late state in the evaluation of the active substance the applicant came with the (new) information that for marine applications a creosote retention of 300 kg/m^3 is needed. During evaluation of biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* Polish CA received information that for sleepers made from beech wood retention of 180 kg/m^3 is needed, for marine applications retention of 400 kg/m^3 is needed.

Numerous studies describing leaching have been presented in creosote dossier. In CAR for creosote RMS selected values which were then used in exposure calculation (Table 2.11).

Table 2.11 Selected leaching rate (i.e. flux) data for PAHs and creosote to use in PEC calculations.

<table>
<tr><th>Reference</th><th>Intended/suitable for scenario/Use Class:</th><th>Flux results from study* (mg/m^2d)</th><th colspan="2">Adjusted flux results for PEC calculations (mg/m^2d)</th></tr>
<tr><td rowspan="2">III-A2.10.2/02
van Dongen, 1987, 1989</td><td>Storage</td><td>Phe 0.0083
Ant 0.00056
Flu 0.0074
B(a)A 0.0063
Creosote 0.33*</td><td colspan="2">Phe 0.015
Ant 0.0010
Flu 0.013
B(a)A 0.011
Creosote 0.57</td></tr>
<tr><td>Use Class 3 (TIME 1)</td><td>Phe 0.0095
Ant 0.00057
Flu 0.0089
B(a)A 0.0051
Creosote 0.35*</td><td colspan="2">Phe 0.0095
Ant 0.00057
Flu 0.0089
B(a)A 0.0051
Creosote 0.35</td></tr>
<tr><td>III-A2.10.2/03 Oldeman & Haverman, 1989
van Dongen, 1987
(continuation of A2.10.2/02)</td><td>Use Class 3 (TIME 2)</td><td>Phe 0.0017
Ant 0.00003
Flu 0.0013
B(a)A 0.00013
Creosote 0.046*</td><td colspan="2">Phe 0.0017
Ant 0.00003
Flu 0.0013
B(a)A 0.00013
Creosote 0.046</td></tr>
<tr><td rowspan="2">III-A2.10.2/07 Berbee, 1989</td><td rowspan="2">Use Class 4a+b and 5 (TIME 1)</td><td rowspan="2">Phe 12.6
Ant 0.85
Flu 4.0
Pyr 2.6
Creosote 100*</td><td>UC4a+b</td><td>Phe 12.6
Ant 0.85
Flu 4.0
Pyr 2.6
Creosote 100</td></tr>
<tr><td>UC5:</td><td>Phe 5.1
Ant 0.35
Flu 1.6
Pyr 1.1
Creosote</td></tr>
</table>

				40.8
	Use Class 4a+b and 5 (TIME 2)	Phe 1.7 Ant 0.33 Flu 0.90 Pyr 0.68 **Creosote 18***	UC4a+b:	Phe 1.7 Ant 0.33 Flu 0.90 Pyr 0.68 **Creosote 18**
			UC5:	Phe 0.69 Ant 0.13 Flu 0.40 Pyr 0.28 **Creosote 7.33**

According to guideline if no new studies have been submitted and if the product applied for authorisation is identical to the representative product in the CAR and the intended use and the exposure to the environment is identical a very short summary of the environmental risk assessment can be presented here which could be copied from the assessment report or from the CAR.

Applicant has submitted new information concerning leaching of creosote or its compounds from treated wood and exposure of environment. Tests submitted by Applicant with application for authorisation were not used in risk assessment. Results of these tests are considered less reliable than tests used in CAR for creosote or the same reliability. However values used in CAR are based on more data. For details please see Doc III.

As for most applications proposed by Applicant exposure to the environment is identical to described in CAR for creosote a short summary of the environmental risk assessment is presented hereafter. Detailed exposure calculation and risk assessment is presented only for **new application - post in agriculture: vineyards**.

Applicant proposed also to consider **application of creosote on sawn wood surfaces by brush.** Although it is the best practice to treat wood in its final form after cutting, shaping and machining sometimes modification of wood components after treatment are necessary and thus wood preservative must be applied again. Railway sleepers and transmission poles are usually treated by brush within industrial impregnation facilities on an impermeable surface. However a modification of wood components may be done also on a construction sites.

To minimise exposure to the environment due to potential spillage during brush application on construction sites to a negligible level risk the mitigation measure without environmental risk assessment was proposed (please refer to point. 2.8.3.2 and 2.9).

Please note also that although different uses of creosote are considered in the environmental risk assessment it does not mean that Applicant has proved lack of appropriate alternatives for creosote for all of these uses (please refer to Annex 8).

The PEC calculations performed in CAR for creosote follow OECD ESD for wood preservatives (OECD, 2003, updated according OECD, 2013 if needed) and the TGD (EC, 2003). Also, the recommendations made in the Report of the Leaching Workshop (EC, 2005) and results of discussions at Technical Meetings (TMs) and Competent Authority (CA) meetings have been taken into consideration when calculating the PECs. The leaching values selected for creosote and creosote components to be used in the calculations can be seen in Table 2.11.

The environmental fate and distribution of creosote is summarised in CAR for creosote and degradation/removal rates and partition coefficients used in the PEC calculations can be found there or in the TGD for certain environmental characteristics.

The local emissions and concentrations are, according to the ESD for wood preservatives (OECD, 2003 updated according OECD 2013 if needed), considered within two different time windows for the service life of treated wood. The initial assessment period (Time 1) is equivalent to the first 30 days of the service life. The duration of the long-term assessment period (time 2) is dependent on several factors such as the retention of wood preservative, the service life of the wood itself which in turn is dependent on the species of wood, and the treatment process. The applicant indicates that for creosote treated wood the service life for use class 3 varies from 25 to 50 years dependent on the species of wood. For use class 4 the applicant expects a service life of 20 years regardless of wood species. In the Report of the Leaching Workshop (EC, 2005) it is concluded that the default service life for vacuum pressure treated wood should be 20 years for use classes 3, 4a and 4b and this time period has also been used for the long-term assessment period in the calculations below. The Report of the Leaching Workshop (EC, 2005) does not suggest a default service life for wood in use class 5. So for simplicity 20 years have been used for the long-term assessment period for this scenario as well.

For the calculations of PECs, creosote retentions up to 150 kg/m^3 (as in CAR) have been taken into consideration. For some very specific use in class 3 (beech railway sleepers) retention up to 180 kg/m^3 is required. For use class 5 retention up to 400 kg/m^3 is proposed by Applicant. Such a high retentions was not evaluated in CAR for creosote. However recalculation of PEC values and new risk assessment is considered not necessary. For explanation please see risk consideration below.

PECs are calculated for both creosote and some of its individual components for uses mentioned in Table 2.12. Details of calculations and results for use of wooden post/stakes in agriculture: vineyards are presented below. Details and results of calculations for other scenarios listed in Table 3 are reported in CAR for creosote (Doc II B).

Table 2.12 Areas of creosote use considered in risk assessment

	Use class	Scenario considered
Industrial use	-	application
	-	storage
In service use	**3**	house/fence[1]/railway sleepers[2]
		noise barrier
		bridge over pond
	4a	transmission pole and fence post[1]
		post in agriculture: vineyards[3]
	4b	jetty in a lake
		sheet pilings in waterway
	5	wharf[2]

[1] Fence scenario and fence post scenario were considered as representative for horse fences.

[2] Applicant recommended higher retention of creosote in comparison to CAR. However recalculation of PEC values and new risk assessment is considered not necessary. For explanation please see section concerning risk.

[3] New use area which was not considered in CAR, therefore calculations of exposure and risk were done

Use of wooden post/stakes in agriculture: vineyards

For this agricultural application, the wooden posts are treated with creosote at the bottom end only, while the upper part remains untreated. These posts are preserved by employing an immersion process, the so-called “hot-and-cold open tank (bath) method” (see DHV 2013: Addendum DOC-IIIA, Section A2.10.2.1/08 and A2.10.2/16).

No monitoring data have been located. The estimation of the potential emissions to the soil from the poles in service follows the same procedure applied in CAR. The only difference is the adjustment of the contact surface to soil and the recipient soil volume around the poles at a radius of 0.5 m.

Calculation of local concentrations/PECs is based on Scenarios developed in the OECD ESD for Wood Preservatives (corresponding to Scenarios for Class 4a Wood in contact with ground – Transmission poles). Specific data for the vineyard scenario were provided by DHV 2013 (German Wood Preserving Association). The volume of treated wood was derived from DIN 68810 (1978) ("Imprägnierte Holzpfähle"), Table 2.13: For poles with a diameter of 8 cm at the top, the preserved volume of 100 posts is stated as 0.550 m^3 with a post height of 2.25 m and a length of 0.8 m for the treated part.

Table 2.13 Dimensions of wooden post/stakes used in vineyards

Length of post [m]	Diameter at top [cm]	Volume (100 posts) [m³]	Length treated [m]	Volume of the treated part (100 posts) [m³]	Mean diameter of the treated part (calculated) [cm]
2.25	ca. 8	1.190	0.8	0.550	9.356
2.25	ca. 8	1.190	0.9	0.636	9.488

According to Applicant’s statement posts of this dimension are usually planted into the ground at a length of about 0.55 m with a residual treated part of 0.25 m above ground. However review of literature concerning procedures for setting up vineyard/orchard indicated that usually (in Poland) post are planted into the ground at a length of 60-70 cm. Therefore additional calculation was made for posts planted into the ground at a length of 0.65 m with a residual treated part of 0.25 m above ground. Using this data, wood areas above and below ground, wood and soil volumes were calculated as default parameter of the scenario.

Table 2.14 Specification post use in vineyard of necessary to calculate emission

Length of post above ground [m]	Length of post below ground [m]	Area of wood above ground [m²]	Area of wood below ground [m²]	Volume of wood below ground [m³]	Depth of soil column [m]	Diameter of soil column [m]	Soil volume to consider [m³]
0.25	0.55	0.07448	0.1617	0.00378	1.05	1.09356	0.9824
0.25	0.65	0.07448	0.1936	0.00459	1.15	1.09488	1.0821

Leaching rates were used in the calculation as recommended in CAR, DOC-IIB, 8.3.1.2, Table 8.3.1.2-1 (above ground: van Dongen 1987/1989 (Time 1) and Oldeman & Haverman 1980/van Dongen 1987 (Time 2); below ground: Berbee 1989 (Time 1 and 2)). Retention of creosote is similar in wood of the leaching studies and in wood for vineyard posts. Therefore, adjustment of leaching rates was not necessary (for details see Table 2).

Calculations of local concentrations (Clocal) were performed as outlined in OECD ESD for Wood Preservatives – Transmission Pole and in the Report to Creosote (PT8) (OECD 2003, see also CAR, DOC-IIB). For the calculation with degradation in soil, the same degradation rate constant (that for creosote) was applied for all individual PAHs. As no leaching data were available for pyrene covering the above soil part of treated wood, leaching data from fluoranthene were used.

Table 2.15 Summary of PECs for creosote and some of its components for the post scenario in vineyards (12 °C, radius 0.5 m, length in ground 55/65 cm)

Scenario	PECs calculated	Creosote	Phe	Ant	Flu	Pyr
Vineyard post -no soil degradation	$PEC_{soil,time1}$ (mg/kg ww)	0.2909/ 0.3161	0.0366/ 0.0398	0.0025/ 0.0026	0.0116/ 0.0126	0.0076/ 0.0082
	$PEC_{soil,time2}$ (mg/kg ww)	12.7372/ 13.8422	1.2021/ 1.3065	0.2333/ 0.2535	0.6365/ 0.6918	0.4810/ 0.5228
Vineyard post -with soil degradation [12 °C]	$PEC_{soil,TW,time1}$ (mg/kg ww)	0.2868/ 0.3171	0.036/ 0.0392	0.0024/ 0.0026	0.0115/ 0.0124	0.0075/ 0.0081
	$PEC_{soil,TW,time2}$ (mg/kg ww)	1.8490/ 2.0066	0.1744/ 0.1894	0.0338/ 0.0367	0.0923/ 0.1	0.0698/ 0.0757

Phe=phenanthrene, Ant=anthracene, Flu=fluoranthene, Pyr=pyrene

time1 = 30 days; time2 = 20 years; ww = wet weight; TW = time weighted values

For comparison, in addition, environmental concentrations of individual PAH were calculated using distinct degradation rates of specific PAH as derived from half-life values reported in CAR, DOC-IIA4.1.1.3.3.

Table 2.16 Summary of PECs for creosote and some of its components for the vineyard post scenario (Degradation in soil based on substance specific rate constants) (12°C, radius 0.5 m, length in ground 55/65 cm)

Scenario	PECs calculated	Creosote	Phe	Ant	Flu	Pyr
Vineyard post -with soil degradation[12 °C]	k_{soil} (/d)	0.009443	0.0105	0.002729	0.0009694	0.001406
	$PEC_{soil,TW,time1}$ (mg/kg ww)	See above	0.0143	0.0011	0.0052	0.0034
	$PEC_{soil,TW,time2}$ (mg/kg ww)	See above	0.0157/ 0.01704	0.0117 /0.01273	0.0899/ 0.09767	0.0469/ 0.05093

Phe = phenanthrene, Ant=anthracene, Flu=fluoranthene, Pyr=pyrene time1 = 30 days; time2 = 20 years; ww = wet weight; TW = time weighted values

2.8.3 Risk assessment

The risk characterisation for the industrial use and for treated wood in-service has been performed both for creosote and for a selection of a few single creosote components.

2.8.3.1 Aquatic compartments

2.8.3.1.1 Sewage treatment plant (STP) – industrial and in-service use

There is a risk posed to micro-organisms in a sewage treatment plant (STP) when an industrial application plant is connected to a STP. The PEC/PNEC ratio was 28 for creosote. **It is therefore proposed that industrial application facilities should not be connected to a local STP.**

The second exposure scenario for a STP is in-service leaching from a noise barrier (use class 3). For this scenario the PEC/PNEC ratio for creosote was <1, i.e. no risk was indicated.

2.8.3.1.2 Surface water – industrial use

The industrial use of creosote generates two exposure pathways to surface waters, emissions from the application entering a local STP followed by discharge into a local surface water and surface runoff from the storage site for creosote treated wood. PEC/PNEC ratios >1 showed that there is a risk posed to aquatic organisms when exposed to creosote and creosote components via STP outlet. **Therefore, it is proposed that industrial application facilities where wood is treated with creosote should not be connected to a local STP.**

PEC/PNEC ratios <1 indicate that no risk is posed to aquatic organisms via exposure to runoff from the storage site. The discharge from a local STP and runoff from the storage site should be assumed to enter the same surface water. In the present case however, there is no point in making this worst-case assumption since the contribution from the storage runoff is negligible compared to the emissions from the application process. In conclusion, the added risk will be the same as the risk for the applications process scenario.

2.8.3.1.3 Surface water – in-service use

No risk is expected to be posed to aquatic organisms from exposure to in-service leaching from a creosote treated noise barrier (via STP outlet) since all PEC/PNEC ratios were <1.

There is risk for aquatic organisms when exposed to in-service leaching from a creosote treated bridge over a small pond (use class 3). The PEC/PNEC ratios for creosote were >1 but for individual creosote components however, the long-term PEC/PNEC ratios indicated no risk to aquatic organisms when removal processes (dissipation) were assumed to affect the creosote components in the water.

For the jetty-in-lake scenario (use class 4b), PEC/PNEC ratios >1 for creosote showed that there is risk to aquatic organisms when exposed to in-service leaching. The ratios were >1 regardless of assessment period or if removal was considered or not. For individual creosote components however, the PEC/PNEC ratios indicated no risk to aquatic organisms when dissipation was assumed to affect the creosote components in the water.

Also measured water concentrations in large mesocosms mimicking the „jetty“ scenario were used in order to assess the risk from in-service leaching. The result showed that there is a risk for aquatic organisms during the initial assessment period but for the long-term assessment period no risk was indicated.

There are risks for aquatic organisms when exposed to in-service leaching from creosote treated sheet pilings in a streaming waterway (use class 4b). The PEC/PNEC ratios were >1 for creosote and >1 for single creosote components.

For the wharf scenario (use class 5), all PEC/PNEC ratios for creosote and for individual creosote components showed that there are risks posed to aquatic organisms when exposed to in-service leaching in a sea water environment. At the authorisation step applicant submitted information that for marine applications a creosote retention of 400 kg/m^3 is needed. Much higher retention certainly caused higher emission to environment and risk. However it is assumed that additional calculations of risk are not necessary. As indicated above and in Table 2.19 not acceptable risk was identified for this application even with retention 150 kg/m^3. Therefore recalculation of risk would not change the conclusion from risk assessment.

Data on measured (by semi-permeable membrane device, SPMD) water concentration adjacent to underwater constructions (piling sites) in a seawater environment was also used to assess the risk for aquatic organisms. The ratio between measured water concentration of creosote and ditto $PNEC_{marine}$ for creosote indicated that risk is posed to aquatic organisms.

2.8.3.1.4 Sediment– industrial use

In a similar manner as for surface water, the PEC/PNEC ratios showed that there is a risk posed to sediment living organisms when exposed to creosote and creosote components from the application process via a STP outlet. No risk is however posed to sediment living organisms via exposure to runoff from the storage site.

2.8.3.1.5 Sediment– in-service use

No risk is posed to sediment living organisms via exposure to in-service leaching from a creosote treated noise barrier (via STP outlet) since all PEC/PNEC ratios were <1.

The PEC/PNEC ratios for creosote and single creosote components for the long-term assessment period were all showing risk for the sediment in the three scenarios; bridge-over-pond, jetty-in-lake and sheet pilings-in-streaming water. For the short-term assessment period for the „bridge scenario, a risk was however only indicated when the PNEC for creosote was not normalised to standard organic carbon content in the sediment.

For the sea water scenario (wharf), a risk was shown for the sediment for the short-term assessment period while for the long-term assessment period a risk was only indicated when the PNECs for creosote and individual components were not normalised to standard organic carbon content in the sediment.

By comparing measured sediment concentration of creosote adjacent to underwater constructions (piling sites) in a seawater environment with the $PNEC_{sediment}$ for creosote (normalised to standard organic content) it was shown that for the initial assessment period there was a risk for sediment living organisms close (0.5 m) to the piling site made of newly treated wood. For the long-term assessment period, at the same piling site, the $PNEC_{sediment}$ for creosote was exceeded (i.e. indicating risk) in surface sediments collected in a gradient from close to the construction and up to a distance of >7.5 m <10 m from the construction. For the piling site made with weathered pilings, the $PNEC_{sediment}$ for creosote was exceeded in sediments collected in a gradient from close to the piling site up to a distance of 2 m for the initial assessment period, and up to a distance of >5 m <10 m for the long-term assessment period.

2.8.3.2 Terrestrial compartment

Industrial use

There is risk posed to terrestrial organisms when exposed to leaching of creosote from treated wood at the storage site. **It is therefore suggested that all treated wood should be stored on impermeable hard standing to prevent direct losses to soil and allow losses to be collected for re-use or disposal.**

Brush treatment

According to Applicant submission it is the best practice to treat wood in its final form after cutting, shaping and machining. Despite this if modification of wood components after treatment are necessary, wood preservative must be applied again on sawn surfaces. This is most typically applied by brush.

Railway sleepers and transmission poles are usually treated by brush within industrial impregnation facilities on an impermeable surface. However as modification of wood components may be done also on a construction sites **it is suggested that during creosote application by brush ground must be covered.**

In such cases exposure to the environment due to potential spillage may be considered as negligible.

In-service use

There is no risk posed to terrestrial organisms by exposure to in-service leaching from creosote treated wood in use class 3 (e.g. house, fence, noise barrier and railway sleepers). All PEC/PNEC ratios were <1 when it was assumed that degradation is taking place in the soil. The use of railway sleepers is represented in the new ESD (OECD, 2013) for wood preservatives. However considering the area of wood exposed to rain relative to the volume of the receiving soil compartment it can be concluded that the „sleeper scenario“ is less worst case than the „house“ scenario of use class 3. Applicant submitted information that retention of biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* in railway sleepers is specific cases is up to 180 kg/m^3 (beech sleepers retention is 150 + 20% = 180 kg/m^3 according to standard PN-D-95014). However even assuming such a high retention, „house“ scenario is considered worst case. Therefore risk assessment for railway sleepers was not recalculated according to new ESD.

There is risk posed to terrestrial organisms when exposed to creosote leached out into the ground from a transmission pole or a fence post (use class 4a). For the transmission pole scenario there is risk for both the initial and long-term assessment periods when assuming soil degradation, while for the fence post scenario the risk was only seen for the long-term assessment period (also when assuming degradation in the soil). For individual creosote components however, the PEC/PNEC ratios indicated no risk when degradation was assumed to affect the creosote components in the soil.

Measured concentrations of creosote (i.e. PAHs) at various distances and depths adjacent to a large number of utility (transmission) poles in service were compared to $PNEC_{soil}$ for creosote. The results indicate that there are risks posed to terrestrial organisms at distances up to at least 76.2 cm from the poles. The PAH concentrations measured at a distance of 122 cm from the poles were not elevated compared to background levels but still some of the samples collected at 122 cm from the poles showed ΣPAH concentrations that were above the PNECsoil, i.e. indicating risk to soil organisms.

Use of wooden post/stakes in agriculture: vineyards

The risks posed to terrestrial organisms from in-service leaching from a vineyard post in the ground are assessed in the tables below. Note: This model calculation also applies to an orchard scenario, e.g. planted with rows of espalier trees.

Table 2.17 PEC/PNEC ratios expected for soil due to emissions of creosote and some of its components from in-service leaching from a creosote-treated vineyard post. Conditions: 12°C, radius 0.5 m, length in ground 55/65 cm

Scenario		PEC_{soil} (mg/kg ww)	$PNEC_{soil}$ (mg/kg ww)	PEC/PNEC
Vineyard post No soil degradation 30 days=TIME 1	Creosote	0.29/0.32	0.30	0.97/**1.07**
	Phenanthrene	0.0370.04	0.45	0.081/0.089
	Anthracene	0.0025/0.0026	0.30	0.0082/0.0087
	Fluoranthene	0.0116/0.0126	0.33	0.035/0.038
	Pyrene	0.0076/0.0082	0.24	0.032/0.034
Vineyard post No soil degradation 20 years=TIME 2	Creosote	12.74/13.84	0.30	**42.46/46.1**
	Phenanthrene	1.20/1.3	0.45	**2.67/2.89**
	Anthracene	0.23/0.25	0.30	0.78/0.83
	Fluoranthene	0.64/0.69	0.33	**1.93/2.09**
	Pyrene	0.48/0.52	0.24	**2.00/2.17**
Vineyard post With soil degradation 30 days=TIME 1	Creosote	0.13/0.31	0.30	0.44/**1.07**
	Phenanthrene	0.016/0.039	0.45	0.036/0.09
	Anthracene	0.0011/0.0026	0.30	0.0037/0.009
	Fluoranthene	0.0052/0.0124	0.33	0.016/0.38
	Pyrene	0.0034/0.0081	0.24	0.014/0.034
Vineyard post With soil degradation 20 years=TIME 2	Creosote	1.85/2.0	0.30	**6.16/6.67**
	Phenanthrene	0.17/0.19	0.45	0. 39/0.42
	Anthracene	0.034/0.037	0.30	0.113/0.12
	Fluoranthene	0.092/0.1	0.33	0.28/0.3
	Pyrene	0.070/0.76	0.24	0.29/0.32

ww = wet weight

Based on the model consideration, there is an apparent risk posed to terrestrial organisms when exposed to creosote leached out into the ground from the vineyard posts.

The risk is predicted for the Time 1 without degradation and particularly for long-term phase with or without degradation taking place in the soil.

Mass balance on creosote leaching:

Based on the long-term leaching rates adopted for these emission scenarios, the amount of creosote released over 20 years accumulates to approx. 25 g per post. According to Applicant's proposal 1100 posts per hectare are used. Review of literature concerning procedures for setting up vineyard indicated that usually posts are planted every 5 m in row, space between rows is 2-2.5 m. Therefore Applicant's proposal is correct. Moreover it is accepted that vineyard should be considered worst case in comparison to orchards. Based on above assumptions approximately 28 kg are emitted per hectare of soil on the average over 20 years. This corresponds to about 4.6% of the initial oil retention in the bottom-end of the posts. The small loss over time is due to the small contact surface of the wood to the soil.

Applicant proposed qualitative risk assessment for this use. However the study used as a basis for assessment (Doc III 2.10.2.14) was not accepted. Therefore qualitative risk assessment is not presented.

<u>Exposure to groundwater</u>

Use class 3

The exposure to groundwater for use class 3 was assessed by simulation with FOCUS PEARL using the „house" scenario. The results showed that the predicted levels of creosote and all individual compounds were <0.001 μg/l for all scenarios.

Use class 4

Exposure to groundwater for use class 4a was assessed by two different simulations with FOCUS PEARL. The first simulation was done according to the same principles as for use class 3, with the only difference that the leaching rate input was the one appropriate for use class 4a. The results showed that the predicted levels of creosote and individual compounds were <0.001 μg/l for all scenarios. The second simulation made use of a special feature in PEARL called soil incorporation. This much more worst case simulation required that the actual wood leaching area of poles was estimated instead of using the default values of the house scenario. The results showed predicted groundwater levels <0.001 μg/l for all individual compounds modelled. For creosote, one scenario out of nine showed a predicted groundwater concentration >0.1 μg/l (0.1066 μg/l). It should be remembered however that the modelling tool (FOCUS PEARL) and the special feature with soil incorporation is an approximate way to assess groundwater exposure for poles in the ground. It is not developed specially to model the leaching of wood preservatives from poles placed in the ground. This in combination with the worst case wood area of poles in a hectare assumed in the simulation leads RMS to consider that exposure to groundwater from in-service use of creosote treated wood in use class 4a is not expected to be an area of concern.

Use of wooden posts in vineyard is a new application compared to CAR for creosote, therefore detailed calculations are presented below.

Exposure to groundwater has been assessed by simulation with FOCUS PEARL. The simulation was performed following the recommendations of document prepared by NL "Calculation of groundwater concentration for substances leaching from wood, masonry and films to soil using PEARL" (TM II 2013). In the document it is proposed to set non-leaching 'parent compound' called 'wall' hereafter which 'degrades' due to leaching into the active substance.

Wall's half-life is derived from the ratio between the amount initially applied and the remaining concentration in the preserved material at the end of its service life.

$$k = \frac{FLUX_{leach}}{Q_{ai}}$$

$$DT_{50} = \frac{\ln(2)}{k}$$

where:

k: degradation constant per day (/d);

DT_{50}: half life (d);

$FLUX_{leach}$: leaching rate (mg/m²/d);

Q_{ai}: total amount of active substance in product (mg/m²)

In the calculation it is assumed that proposed by Applicant retention of creosote – 90 kg/m^3 corresponds to 180000 mg/m^2. Moreover leaching rate of creosote during Time 2 is 18 mg/m^2 d according to CAR (Doc II B, Table 8.3.1.2.-1) was used. This result in DT_{50} of parent compound equals 6931 days:

Input parameters for parent compound have been adopted from document prepared by NL.

The parent compound is completely stable and immobile in soils by setting vapour pressure and water solubility to its absolute minimum ($1 \cdot 10^{-7}$ Pa, and 0.001 mg/L, respectively) to ensure that it will not evaporate (resulting Henry's constant is as low as possible) or dissolve. However, the molar mass is identical to that of the active substance. Most important is the Koc of the wall, which should be at least $1.0 \cdot 10^{6}$ L/kg (pH independent) and the Freundlich coefficient set to one to guarantee maximum adsorption to the soil's organic matrix.

Input parameters for creosote and some individual compounds have been adopted from CAR for Creosote prepared by SE (Doc IIB, Appendix III B).

Parameters of PEARL have been set as follow: crop - grass, soil incorporation at a depth of 0.2 m, applications starting February 15, simulated application every year for 66 years. Crop uptake was set to zero for worst case. Assuming leaching from one pole during Time 2 of 0.02546 kg dose per hectare is 1.4 kg/ year.

Table 2.18 Results of simulation of groundwater concentration made with FOCUS PEARL

Substance	FOCUS Pearl Scenario								
	HAM	CHA	JOK	KRE	OKE	PIA	POR	SEV	THI
Creosote	0	0	0	0	0	0	0	0	0
Phenanthrene	0	0	0	0	0	0	0	0	0
Anthracene	0	0	0	0	0	0	0	0	0
Fluoranthene	0	0	0	0	0	0	0	0	0

Atmosphere

Creosote released from the industrial application process and during storage and in-service use of creosote treated wood is not expected to result in air concentrations which can be considered to be of concern.

Table 2.19 Summary of the results of the risk characterisation for industrial and in-service use of creosote.

		PEC/PNEC >1 (i.e. indicate risk), Yes / No				Measured concentrations indicate risk? Yes/No (Conc./PNEC ratio)
Use scenario		**STP**	**Water**	**Sediment**	**Soil**	
Application - industrial		yes	yes	yes	-	-
Storage		-	no	no	yes	-
Application by brush on a construction site		-	-	-	n.r.[6]	-
Use class	**In-service use scenario**					
3	house/fence/railway sleepers	-	-	-	no	-
	noise barrier	no	no	no	no	-
	bridge over pond	-	yes	yes	-	-
4a	transmission pole and fence post	-	-	-	yes	yes (24)[1]
	post in agriculture: vineyards[1]	-	-	-	yes	-
4b	jetty in a lake	-	yes	yes	-	no - water[2]
	sheet pilings in waterway	-	yes	yes	-	-
5	wharf[2]	-	yes	no[5]	-	yes (4) – water[3] yes – sediment[4]

[1] The ratio given is for soil at a distance of 45.7 cm from transmission/utility poles (long-term assessment).

[2] The ratio given is for water (large mesocosms) for the long-term assessment period.

[3-4] Equivalent to the long-term assessment period.

[5] The result in the table was obtained when using sediment carbon normalised PNEC for creosote. The result when using a non-normalised PNEC value indicated risk.

[6] Risk was not calculated as covering of ground during creosote brush application will result in negligible exposure to environment

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

The risk for secondary poisoning via the aquatic and terrestrial food chain was assessed for the creosote constituents anthracene, fluoranthene, and pyrene, for which there were data available. The ratios for PEC_{oral} predator/$PNEC_{oral}$ were all <1 and thus the results of the assessment indicate that the risk for secondary poisoning is low from exposure to creosote components leaching from treated wood in service.

PBT assessment

The PBT assessment prepared for creosote is applicable for biocidal product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C*. The conclusion from assessment made for creosote does not change. However as compartment specific risk assessment the PBT assessment can influence final decision concerning biocidal product family. Therefore summary of PBT assessment form CAR is presented hereafter. The PBT assessment made according to the criteria described in the TGD concluded that some creosote components fulfil one or more of the P, B or T criteria while other components do not. Anthracene has been reviewed by the PBT working group under the Technical Committee for New and Existing Substances (TC NEC) which concluded that this compound fulfils the PBT criteria. According to the data in the dossier for creosote no other compounds fulfils the PBT criteria. Fluoranthene and pyrene fulfils the P and T criteria and when theoretically estimated; also the B criterion why these compounds may be considered as potential PBT substances.

CAR for creosote contains information that in the document by ECHA, *Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern*, from 2007 it is stated that a multi-constituent substance composed of one or more constituents in individual amounts of ≥0.1% but <80% having PBT- or vPvB properties should be named "the substance contains PBT, or vPvB constituents". Since the content of anthracene which has documented PBT properties is approximately 1% in creosote RMS proposes that creosote should be described as a substance containing PBT constituents. In the more recent document from 2014 this is confirmed. In *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.11: PBT/vPvB assessment it is stated that constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation. In *Guidance on Information Requirements and Chemical*

Safety Assessment Part C: PBT/vPvB assessment it is stated generally, if a substance contains one or more constituents, impurities and/or additives with PBT/vPvB properties in individual amounts ≥0.1% (w/w) or if transformation/degradation products with the PBT/vPvB properties in relevant amounts are being generated, the substance must be considered as PBT/vPvB.

2.9 Measures to protect man, animals and the environment

1. Stringent adherence of the protecting measures that are already in place.
2. Respiratory protection, such as a full face mask with particle filter P2 or preferably P3 in combination with gas filter A (brown) should be worn at critical work tasks when there is a risk of inhalation exposure.
3. Chemical resistant (coated) coveralls, or equivalent, should be worn over the regular work clothes at critical work tasks when there is a risk of exposure, and a thinner pair of (cotton) gloves should be worn under the chemical resistant gloves.
4. Creosote-resistant boots should be worn when entering the vessel (e.g. for cleaning or maintenance).
5. In order to ensure efficient protection, tight sealings (sleeve capes) may be used at the border of different garments, e.g., at the border of gloves and sleeves and at the border of trousers and boots.
6. The PPE should be changed frequently, and immediately after contamination. Inhalational PPE shall be changed at required intervals.
7. Whenever possible, mechanical or automated processes should be used to avoid manual handling of treated timber (including down-stream work, for example during work with poles in service).
8. The personal hygiene shall be strict, and washing with suitable cleaning solutions shall be performed as soon as possible after each work task where there is a risk of exposure.
9. The working areas such as the treatment/equalisation hall shall be cleaned when judged necessary based on monitoring or inspections. Other areas such as changing and washing rooms, break rooms and control rooms shall be cleaned weekly. Relevant equipment and tools shall be cleaned in case of contamination.
10. Where there is a potential contact with creosote or creosoted wood, long sleeves shirts and long pants must be worn.

11. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
12. If on skin: Wash with plenty of soap and water.
13. Application by brush should take place on temporary bounded impervious surface (such as plastic membrane).
14. Treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.
15. The treated wood is not placed on the market until it is dry.
16. Avoid release to the environment. Refer to special instructions/safety data sheet.
17. Avoid contamination of soil, surface water or sanitary sewer system from product or packaging the product.
18. In case of accidental release of product into the environment, it should be collected with non-combustible, absorbent material e.g. sand, earth, vermiculite and place in labeled and colder container for disposal and deliver to authorised company which are empowered to utilization of hazardous wastes and their disposal. During collect avoid direct contact with the skin.
19. If the product contaminates lakes, rivers, or sewers, inform the appropriate authorities in accordance with local regulations.
20. Product should be stored in original, labelled and closed containers in cool, dry and well-ventilated area.
21. This material and its container must be disposed of in a safe way.
22. The industrial application facilities where wood is treated with creosote should not be connected to a local STP.

<u>Additional measurements for pole installers:</u>

1. Strict adherence to proper working conditions.
2. Increased use of aerial access platforms (exposure is clearly connected to close contact with the poles).
3. Hand and face wash possibilities in the field.
4. Use of light chemical resistant coveralls.
5. Use of dry poles (wet poles can be returned to the impregnation plants, and use of sectorially impregnated poles, the poles may be more impregnated at the bottom

regions that are in contact with the ground and less impregnated at regions that are above the ground).

2.10 Proposal for decision

Although some of the efficacy data are old, they nevertheless, together with many years of practical experience, adequately show the good efficiency of creosote against a broad spectrum of harmful organisms.
The efficacy data supports application rate for penetrating treatment against target organisms with *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* declared by applicant.
Based on the risk characterisation presented in the DOCII-C of the CAR and a comparison with the estimated exposure levels in the additional work scenarios presented in this product assessment report, a risk for professional and industrial users resulting from the intended uses is not expected when personal protective equipment (gloves and coverall) are worn. It was concluded in the CAR for creosote that there are sufficient Margin of Exposures (MOEs) at the European impregnation plants, and that the exposure levels are below a Derived Minimal Effect Level (DMEL), which represents a risk level, that according to available guidance, is of low concern (10^{-5}).

In the CAR, acceptable uses were identified as far as acceptable uses can be said to exist for a genotoxic carcinogen.

Furthermore, it is estimated that the exposure situation can be further improved by extra protective measures during work tasks where there is a risk of exposure.

No environmental risks were identified for the terrestrial compartment when treated wood is used without cover and without contact with soil (use class 3). However risks were identified for all other use areas. Moreover *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* contains PBT constituents. Therefore should not normally be authorised.

Nevertheless, based on the alanysis of potential alternatives for creosote-treated wood performed in relation to this application according to point 15 of Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I and also in line with article 23 of regulation EU No 528/2012 (BPR) there are no sufficient alternatives available on Polish market for some of uses which are considered in this document (please see Annex 8).

Therefore, the product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* may be authorised only in use classes 3 and 4 for:

- **impregnation of wooden sleepers and poles;**
- **impregnation in an agricultural sector e.g. fruit tree and hop/vineyard stakes, fences, anti-hail curtains).**

Authorisation can be granted for a period not longer than 5 years based on article 23 point 6 of BPR.

For other uses (impregnation of noise or snow barrier, horse fence and for use in marine installations) there was no sufficient information submitted to prove that there are no alternatives for creosote product. Therefore these uses can not be authorized in Poland (for details please refer to Annex 8).

Annex 1: List of studies reviewed

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIA	A2.10.1/08 (IIB, 8.3.2.2.4)	DHV	2013a	Data information: Impregnation process, technical data, applicatiion modalities, scenarios	Deutscher Holzschutzverband (DHV) [German Wood Protecting Association]	☒	☐	☒	☐
IIIA	A2.10.1/08 (IIB, 8.3.2.2.4)	DIN	1978	Imprägnierte Holzpfähle	Public	☐	☒	☐	☒
IIIA	A2.10.1/08	VDI	2012	Anforderungen an Hölzer nach ihrer Behandlung im Heiss-Kalt-Einstelltränkverfahren. (Draft), included in DHV 2013b	(not yet) public	☐	☒	☐	☒
IIIA	A2.10.1/09	WPA	2013	Data information: Creosote cut end treatment	The Wood Protection Association / UK	☒	☐	☒	☐
IIIA	A2.10.1/10	Habert C., Guinot C., Fernandez G., Garnier R.	2002	Evaluation de l'exposition aux hydrocarbures aromatiques polycycliques lors de l'usinage de traverses créosotées	Société Nationale des Chemins de Fer français (SNCF)	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIA	A2.10.2/14	Jernlås R.	2012	Status Report on Soil Contamination in the Proximity of Creosote-Treated In-Service Utility Poles in Sweden	International Research Group on Wood Preservation (IRG) / - Wood-Preservation Industry of Europe (WEI) (Brussels) / - Creosote Council Europe (CCE) (Brussels)	☒	☐	☒	☐
IIIA	A2.10.2/15 A2.10.2/16	DHV	2013b	Data information: Impregnation process, technical data, applicatiion modalities, scenarios	Deutscher Holzschutzverband (DHV) [German Wood Protecting Association]	☒	☐	☒	☐
IIIA	A2.10.2/16 (IIB, 8.3.2.2.4)	DHV	2013	Kreosot fuer die Verwendung im Agra(Industrie-)bereich – Daten und Informationen	Deutscher Holzschutzverband (DHV) [German Wood Protecting Association]	☒	☐	☒	☐
IIIA	A2.10.2/16 (IIB, 8.3.2.2.4	DIN	1978	Imprägnierte Holzpfähle	public	☐	☒	☐	☒

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIA	A2.10.2/17	Hudson N. J., Murphy R. J.	1997	Losses of CCA Components and Creosote from treated timber to soil	- International Research Group on Wood Preservation (IRG) / - Wood-Preservation Industry of Europe (WEI) (Brussels) / - Creosote Council Europe (CCE) (Brussels)	☒	☐	☒	☐
IIIA	A2.10.2/17	Bergqvist G. and Holmroos S.	1994	Analysis of creosoted posts after 40 years of exposure	International Research Group on Wood Preservation (IRG) / - Wood-Preservation Industry of Europe (WEI) (Brussels) / - Creosote Council Europe (CCE) (Brussels)	☒	☐	☒	☐
IIIA	A2.10.2/18	Marechal B., Favre M. C.	2013	Impact des traverses créosotées sur les ballasts et les sols au droit des voies ferrées	Société Nationale des Chemins de Fer français (SNCF)	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIA	A.2.10.2/19a	Andersson-Sköld Y., Toomväli C., Larsson L., Nilsson P., Hemström K., Enell A.	2008a	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Ytutlakning av PAH från kreosotimpregnerade sliprar., Varia 587	Trafikverket, Sweden	☒	☐	☒	☐
IIIA	A.2.10.2/19a	Andersson-Sköld Y., Toomväli C., Larsson L., Nilsson P., Hemström K., Enell A.	2008b	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Ytutlakning av PAH från kreosotimpregnerade sliprar. Annex: Methods and Results Tables	Trafikverket, Sweden	☒	☐	☒	☐
IIIA	A.2.10.2/19b	Enell A., Hemström K., Nilsson P., Andersson-Sköld Y.	2008a	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Fastläggnings- och desorptionstest av PAH	Trafikverket, Sweden	☒	☐	☒	☐
IIIA	A.2.10.2/19b	Enell A., Hemström K., Nilsson P, Andersson-Sköld Y.	2008a	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Fastläggnings- och desorptionstest av PAH	Trafikverket, Sweden	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIA	A.2.10.2/19b	Enell A., Hemström K., Nilsson P., Andersson-Sköld Y.	2008b	Kreosotimpregnerade sliprars inverkan på spridning av kreosot i mark – Fastläggnings- och desorptionstest av PAH Annex: Methods and Results Tables	Trafikverket, Sweden	☒	☐	☒	☐
IIIA	A7.2.2.1	Volkering F., Breure A. M.	2003	Biodegradation and general aspects of bioavailability, in: PAHs – An Ecotoxicological Perspective (ed. Douben PET),	public	☐	☒	☐	☒
IIIA	A7.4.1.2/06 (IIA, 4.2.1.2)	Aniol S., Blum Th., Honnen W.	2009a	Daphnia sp., Acute Immobilisation Test according to OECD 202 of Wash Oil, 18 March 2009	CCSG/CCE (Brussels)	☒	☐	☒	☐
IIIA	A7.4.1.2/07 (IIA, 4.2.1.2)	Aniol S., Blum Th., Honnen W.	2009b	Daphnia sp., Acute Immobilisation Test according to OECD 202 of Anthracene Oil (BaP >50 ppm), 25 March 2009	CCSG/CCE (Brussels)	☒	☐	☒	☐

Annex 2: Analytical methods residues – active substance

< Creosote >

Additional data for validation of analitical method for identification in soil was pressented.

Annex 3: Toxicology and metabolism – active substance

<Creosote>

Threshold Limits and other Values for Human Health Risk Assessment

Summary		
	Value	**Study**
AEL	Creosote is classified as H350 Carc. 1B. According to the EU guidance on AOEL setting (rev 10), an AOEL cannot be set for substances that are genotoxic and/or carcinogenic unless a threshold mechanism clearly has been demonstrated.	
NOAEL $_{dermal}$	400 mg/kg bw/day	Subchronic dermal toxicity test
NOAEL $_{inhalation}$	22 mg/m^3	Subchronic 90-day inhalation toxicity test in rats
NOAEL $_{teratogenicity}$	50 mg/kg bw/day	Teratogenicity test (rat, rabbit: oral)
NOAEL $_{reproduction}$	25 mg/kg bw/day	Two generations reproduction study in rats
CorrT25	1690 mg/kg bw/Day	Dermal cancer study in mice
DMEL	68 µg/kg bw/Day	-----

Inhalative absorption	100% used
Oral absorption	Considered as not relevant (impossible to assess, since creosote consists of several 100 compounds)
Dermal absorption	10% and 5% to be included

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
according to EC 1272/2008	
Classification	
H315	Causes skin irritation

H317	May cause an allergic skin reaction
H350	May cause cancer
H360F	May damage fertility
H361d	Suspected of damaging the unborn child
Labelling	
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H350	May cause cancer
H360F	May damage fertility
H361d	Suspected of damaging the unborn child
Picotgrams	
Signal word	Danger

Annex 4: Toxicology – biocidal product family

<*Olej kreozotowy gatunek B* *Olej kreozotowy gatunek C*>

General information	
Formulation Type	Liquid
Active substance(s) (incl. content)	Creosote 100%
Category	PT 8 – wood preservatives

Acute toxicity, irritancy and skin sensitisation of the preparation (the same as for the active substance)	
Rat LD_{50} oral (OECD 420)	>3500 mg/kg
Rat LD_{50} dermal (OECD 402)	>2000 mg/kg
Rat LC_{50} inhalation (OECD 403)	>5000 mg/m^3 (aerosol)
Skin irritation (OECD 404)	Irritating
Eye irritation (OECD 405)	Not irritating
Skin sensitisation (OECD 429; LLNA)	Positive (Maximization) negative (Buehler)

Additional toxicological information (the same as for the active substance)	
Repeated dose toxicity	Lowest relevant dermal NOAEL – 400 mg/kg bw/d (90 d) Lowest relevant inhalation NOAEL – 22/128 mg/m^3 (90 d)
Bacterial reverse mutation test (Ames test) In Vitro mammalian chromosome aberration test (human lymphocytes) In vitro mammalian cell gene mutation test (Mouse lymphoma L5178Y) In vivo micronucleus assay (mouse, bone marrow) Dominant-Lethal Test (rat)	Positive (+ S9), negative (- S9) EU negative (+/- S9) positive (weak, + S9) negative negative

Additional toxicological information (the same as for the active substance)	
Long term toxicity and Carcinogenicity	lowest dose with tumours – 0.1 mg (2x/wk)
Reproductive toxicity	Lowest relevant reproductive NOAEL – 25/75 mg/kg bw/d Lowest relevant developmental NOAEL – 50/175 mg/kg bw/d

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
according to EC 1272/2008	
Classification	
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H350	May cause cancer
H360F	May damage fertility
H361d	Suspected of damaging the unborn child
Labelling	
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H350	May cause cancer
H360F	May damage fertility
H361d	Suspected of damaging the unborn child
Picotgrams	
Signal word	Danger

Annex 5: Safety for professional and industrial operators

<Olej kreozotowy gatunek B Olej kreozotowy gatunek C>

Exposure assessment

Exposure scenarios for intended uses (as presented in CAR)

European plants (FIOH 2008a and Van Rooij et al. 1993)

Table 1. PPE and job tasks (FIOH 2008a)

	Wood treatment operator 1	Wood treatment operator 2	Wood treatment operator 3	Maintenance operator
Respiratory protection	Half mask A2B2E2K2-P2	Full mask A2B2E2K2-P3	Full mask A2B2E2K2-P3	Half mask A2B2E2K2-P2
Hand protection	Nitrile gloves Ansell Hycron 27-607	Nitrile gloves Ansell Hycron 27-607	Nitrile gloves Ansell Hycron 27-607+ Maxiflex plus 34-844	Nitrile glovesAnsell Hycron 27-607, leather gloves (welding)
Changing of gloves	Changed five shifts ago	Changed four shifts ago	Changed two shifts ago	Changed on the same day
Face/eye protection	Half mask	Full mask	Full mask	Goggles or a welding mask
Working clothes	Jacket and trousers*, safety shoes	Jacket and trousers*, safety shoes	Jacket and trousers*, safety shoes	Cotton overall**, safety shoes
Changing the working clothes	At least weekly, immediately upon contamination	At least weekly, immediately upon contamination	At least weekly, immediately upon contamination	Almost daily
Washing hands	With soap several times during the shift	Before breaks	After each load change; also washed his face	As required during the shift
Creosote work on the day of the measuring	Unloading and charging an impregnation cylinder,	Unloading and charging an impregnation cylinder,	Unloading and charging an impregnation cylinder twice,	Repairing a creosote buggy (1h), replacing

	unloading and charging an after-treatment cylinder	starting to unload a creosote railway car	charging an after-treatment cylinder, participation in replacing a gasket, unloading a creosote railway car	a creosote cylinder gasket (0.5 h)

* Material: 70% polyester, 30% cotton 230 g/m^2
** Material: 100% cotton 290 g/m^2

Table 2: Skin exposure to pyrene and creosote of workers at European impregnation plants

		FIOH 2008		Van Rooij et al. 1993	
	Exposure variable per day	**Averages**	**Ranges**	**Averages**	**Ranges**
				With additional coverall	
				Without additional coverall	
IA	Pyrene, hand [ng/cm^2]	2.22	0.6-53	30-40	--
				82	
IB	Creosote, hand (estimated) [ng/cm^2]	738[1)]	20-1767[1)]	1000-1330[1)]	--
				2730[1)]	--
IIA	Pyrene, total skin [µg/kg bw]	1.2-1.7[4)]	0.04-4.1[3)]	1.9	1.5-5.7
				6.3	0.6-18.7
IIB	Creosote, total skin (estimated) [µg/kg bw]	40-57[2)]	1.5-136[3)]	71.9[2)]	17-190[2)]
				210[2)]	20-623[2)]

[1)] Calculated from corresponding Pyrene values (line IA) by dividing by the pyrene concentration in EU creosote of 3% (factor 1/0.03).

[2)] Calculated from corresponding Pyrene values (line IIA) by dividing by the pyrene concentration in EU creosote of 3% (factor 1/0.03).

[3)] Calculated based on findings van Rooij et al. (ratios of line IIA/IA and IIB/IB, resp., multiplied with ranges): hand contamination is known for both studies, assumption: relative amount hand/body is assumed to be the same: Calculations examples 1.9/35 x low range, 6.3/82 x high range; 63/1170 x low range; 210/2730 x high range (FIN).

[4)] Calculated from corresponding Pyrene values (line IA van Rooij et al.), multiplied with the ratio Pyrene (hand) (line A): calculation: 6.3 x 22.2/82 = 1.7; 1.9 x 22.2/35 = 1.2, with 35 the arithmetic mean of 30 + 40.

Exposure of down-stream users (pole installers – Mäkelä et al. 2008).

Table 3. Average concentrations of PAHs [ng/cm^2] found on the hands of workers during pole furnishing (A), during installation of conductors (B), and during installation of a separator (C)

Component	A			B			C			
	Morning	Noon	After shift	Morning	Noon	After shift	Morning	Noon	Afternoon (“before coffee break”)	After shift
	[ng/cm^2]			[ng/cm^2]			[ng/cm^2]			
Naphthalene	-	-	-	0.1	0.1	0.2	-	-	-	-
Acenaphthene	-	-	-	-	-	-	-	-	-	-
Fluorene	-	-	-	-	-	-	<20	40	30	<20
Phenanthrene	1.3	8.5	6.0	2.5	3.7	5.8	350	1000	1240	420
Anthracene	-	-	-	-	0.1	0.1	-	<20	1200	400
Fluoranthene	2.5	26.0	19.0	3.7	5.7	10.1	140	400	520	220
Pyrene	1.5	14.5	11.0	2.3	4.0	6.4	60	400	780	350
Benz[a]anthracene	-	-	-	0.2	0.6	0.3	-	<20	250	120
Chrysene	0.5	2.5	2.0	0.4	0.5	0.8	-	-	<20	<20
Benzo[b]fluoranthene	<0.5	<0.5	0.7	-	-	-	-	-	<20	-

Benzo[k]fluoranthene	-	<0.5	<0.5	-	-	-	-	-	-	-
Benzo[a]pyrene	-	<0,5	<0,5	-	-	-	-	-	-	-
Indeno[1.2.3-cd]pyrene	-	-	-	-	-	-	-	-	-	-
Dibenz[a.h]anthracene	-	-	-	-	-	-	-	-	-	-
Benzo[ghi]perylene	-	<0.5	<0.5	-	-	-	-	-	-	-

Additional exposure scenarios for intended uses (not assessed in CAR)

Brush treatment of wooden constructions:

Inhalation exposure

The following table summarises the ranges of air concentrations measured under various workplace conditions during wood impregnation, during surrounding operations or follow-up activities:

Table 4. Overview of PAH levels in air during wood treatment operations

Process / operation	Sum PAHs [mg/m³]#	Environment and type of measurement		Source
Pressure process (Rüping)	0.5-70	outside/inside	stationary	Hebisch et al. 2009
	0.7-5.1	inside	stationary	FIOH 2008a
	0.1-0.15	outside	stationary	
	0.04-1.29 (Naph.)	outside/inside	personal	Bookbinder 2001
	0.3-0.4	outside/inside	personal	Borak et al. 2002
Railway ties: plating, assembly	≤6.8	inside	stationary	Hebisch et al. 2009
	0.35-0.51	outside	stationary	
Non-pressure process	0.12-3.3	Inside/semi-open - outside	stationary	Hebisch et al. 2009
Furnishing and installation of utility poles	<0.04 – 0.09	outside	personal	Mäkelä et al. 2008

Emission rates / mass flows to air /evaporation rates

Based on a model study using freshly creosote-treated wood posts (pine, aged for 18 hours, length 100 cm and diameter 9 cm) under controlled conditions in a test chamber, the emission rate of PAHs ranged between 4 and 35 mg/(m^2*d) (Σvolatile EPA PAHs, predominantly naphthalene, acenaphthene, fluorene, and phenanthrene) (see Homan and Beckers 1994). Note: The creosote used was WEI Type C (Grade C), which means that the fraction of volatiles is reduced compared to WEI Type B (Grade B).

For cut-end treatment, the maximum treated wood area per shift is taken as basis for estimating the "worst-case" emission from freshly re-treated surfaces. This is about 3.6 m^2/h.

Maximum emission under test condition:

35 mg/(m^2*d)/24 h = 1.5 mg/(m^2*h)

First estimate of an emission rate during cut-end treatment:

3.6 m^2*1.5 mg/(m^2*h) = 5.4 mg/(m^2*h).

Assessment factor (AF) for volatility: AF = 2.5 (This AF is to compensate for increased evaporation in case a creosote Grade B has been applied.)

Assessment factor (AF) for aging: AF = 10 (It is assumed that the initial evaporation rate after brushing is 10 fold higher than after 18 h storage.)

Final estimate for an emission rate (ER) during cut-end treatment:

ER = 5.4 mg/(m^2*h)*25 m^2 = 135 mg/h.

Air concentrations

Assumptions:

Primary distribution volume = 100 m^3, ventilation rate 10/h,

=> air flow (F) = 1000 m^3/h

The stationary air concentration would result in

ER/F = 135 mg/h/(1000 m^3/h) = 0.135 mg/m^3.

Exposure of workers processing/machining creosote-treated wood

Table 5, TEF of 16 PAHs considered in the report as markers of creosote

PAHs	Number of rings	IARC classification	TEF [1] from AFSSA [3]	TEF [1] from US EPA [2]
benzo(a)pyrene	5	2A	1	1
dibenzo(ah)anthracene	5	2A	1	1
benzo(b+j)fluoranthene	4	2B	0.1	1
benzo(k)fluoranthene	4	2B	0.1	1
indenopyrene	5	2B	0.1	1

benz(a)anthracene	4	2A	0.1	1
chrysene	4	3	0.01	1
benzo(ghi)perylene	6	3	0.01	0
fluoranthene	3	3	0.01	0
anthracene	3	3	0.01	0
pyrene	4	3	0.001	0
phenanthrene	3	3	0.001	0
fluorene	2	3	0.001	0
acenaphthene	2	-	0.001	0
acenaphthylene	2	-	0.001	0
naphthalene	2	-	0.001	0

1) A Toxicity Equivalency Factor (TEF) has been developed for each PAH representing a relative potency of toxicity by comparison with the toxicity of B(a)P. The addition of the 16 PAH atmospheric concentrations based on their TEF was expressed as B(a)P equivalency.

2) EPA assessed the risks of PAH mixtures by assuming that all carcinogenic heavy PAHs were as potent as benzo[*a*]pyrene (B[*a*]P), one of the most potent PAHs. Therefore, TEF values were 1, while "light" PAHs (two to four rings) were not considered, leading to TEF value of 0.

3) The approach of AFSSA considered both the carcinogenic PAHs (TEFs $\geq$ 0.01) and the non-carcinogenic PAHs (TEFs $<$ 0.01).

Annex 6: Safety for non-professional operators and the general public

<Olej kreozotowy gatunek B
Olej kreozotowy gatunek C>

The product family is not intended for non-professional users (see section 2.7.2.2 of this PAR)

Annex 7: Residue behaviour

<Creosote>

According to Assessment Report for creosote before authorization of biocidal product *validation data for a monitoring method for soil and data on route of degradation in soil and the extent and nature of bound residues* must be provided.

The data submitted by Applicant concerning the route of degradation and possible toxic metabolites are considered to be sufficient for the present product authorisation application. However, for an application of renewal of the active substance approval, a more thorough inspection of the data is needed.

Annex 8: Comparative assessment

1. Background

Poland is a reference Member State for a national authorisation of biocidal product family: *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* which contains creosote as the active substance.

Creosote has been classified in accordance with Regulation (EC) No 1272/2008[4] as a carcinogen in category 1B; H350 and contains constituents that have been considered as PBT (persistent, bioaccumulative and toxic) in accordance with the criteria set out in Annex XIII to Regulation (EC) No 1907/2006[5,6]. Creosote fulfils therefore the exclusion criteria according to Article 5.1(a) and (e) of the Biocidal Products Regulation (EU) No 528/2012 (BPR)[7] and should consequently, in line with Article 10.1(a) of the BPR, be regarded as a candidate for substitution.

Moreover, according to point 15 of Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I of the Directive 98/8/EC (BPD)[8], biocidal products containing creosote may be authorised only for applications where all local and other circumstances have been taken into account and no appropriate alternatives were found.

Presented document has been created to address this issue and in line with Article 23(1) of BPR.

This comparative assessment is focused on the use areas specified in the application for product authorisation which are intended for the products in Poland and potential alternative wood preservatives or non-chemical methods that are applicable to use in Poland. The following use areas are addressed in this assessment:

- Railway sleepers

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[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[5] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[6] The Committee for Risk Assessment of the European Chemicals Agency has considered the constituent anthracene to be persistent, bioaccumulative and toxic (PBT) and fluoranthene, phenanthrene and pyrene to be very persistent and very bioaccumulative (vPvB).

[7] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

[5]Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

- Poles (electric power transmission and telecommunications)
- Fence posts for use in the agricultural sector
- Horse fence
- Noise barrier
- Snow barrier
- Marine installations

2. Legislation and guidance

Article 23 of the BPR lays down the conditions for a comparative assessment of biocidal products. According to Article 23(3) the receiving competent authority shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where a comparative assessment, demonstrates that both of the following criteria are met:

a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;
b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

The comparative assessment shall be performed in accordance with the technical guidance notes referred to in Article 24 and is based on the "Technical Guidance Note on comparative assessment of biocidal products"; CA-May15-Docc.4.3a-Final.

<u>Specific provision according to the Commission directive 2011/71/EU</u>

As recognised above, the inclusion directive for creosote includes a specific provision stating that products containing creosote may only be authorised for uses where the authorising Member State concludes that no appropriate alternatives are available. The conclusions shall be based on an analysis regarding the technical and economic feasibility of substitution which it shall request from the applicant, as well as on any other information available to it.

No guidance have been developed under the biocidal products directive 98/8/EC (BPD) in order to facilitate for applicants or authorising Member States how to comply with this provision. Poland considers that this comparative assessment made in accordance with Article 23 of the BPR covers the aspects that shall be considered according to the specific provision. In accordance with the specific provision for creosote the Member state can only authorise a creosote containing product if their analysis show that there are no alternatives available. Hence, there is a difference to the provisions in Article 23 of the BPR, where in order to prohibit a product if must be demonstrated that both criteria in Article 23 of the BPR are fulfilled.

3. Administrative details and Administrative information of the Biocidal Product Family:

Procedure:	NA
Purpose:	Authorisation of a biocidal products family
Case Number in R4BP:	BC-DT010405-39
Evaluating Competent Authority:	PL The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Applicant:	Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp.z o.o.
(Prospective) Authorisation holder:	Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp.z o.o.
Trade names:	Olej kreozotowy gatunek B Olej kreozotowy gatunek C
Product type:	8 (Wood Preservatives)
Active substance:	creosote (100%), CAS: 8001-58-9

4. Intended uses of the Biocidal Product Family:

<u>Uses intended in Poland</u>

The applicant has applied for the following uses of the *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* products in Poland as are presented in table 4.1 below.

Table 4.1 . Intended uses	
Product Type	PT8 Wood preservatives
Aim of treatment	Preventive protection
Use class wood	UC 3 UC 4a UC 4b *UC 5*[*]

Target organism (including, where relevant) development stage)	Wood rotting fungi (wood rotting basidiomycetes, soft rot micro-fungi, wood disfiguring fungi) Wood rot in soil and water contact Insects (termites, wood-decaying beetles) Marine crustaceæ and molluscs (marine borers).*
Field of use	• Wood sleepers • Wood poles for transmission of electric power and telecommunications • Impregnation the agricultural sector e.g fruit tree and hop/vineyard stakes, fences, anti-hail curtains • Horse fences* • Noise barrier***** • Snow barier* • Marine installations*****
Application method	1) Vacuum pressure impregnation 2) Hot-and-cold open tank (bath) method 3) Brush treatment of wooden constructions
Application rate	Use class 3: • 50-120 kg/m^3 for softwood • 40-150 kg/m^3 for hardwood Use class 4: • 75-130 kg/m^3 for softwood • 20-150[9] kg/m^3 for hardwood Use class 5:***** • 156-400 kg/m^3 for softwood • 156-400 kg/m^3 for hardwood
Category of users	professional and industrial

* These uses have been not authorised in Poland

5. Existing alternative biocidal products

PL CA has reviewed the biocidal products on Polish market in search of the biocidal products which can be considered as alternatives for *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C*. The biocidal products authorised for some of the intended uses as relevant the biocidal product shall be considered as eligible alternative biocidal product. In accordance

[9] in case of railway sleepers higher retention – up to 180 kg/m^3 is required

with the “Technical Guidance Note on comparative assessment of biocidal products” CA-May 15-Doc.4.3.a-Final, the existing products placed on the market of Poland according to the national systems operating during the transitional period have been excluded from the comparison.

In Poland there are many biocidal products authorised for PT8 but in large part they have been intended to be used for protection of wood in UC2 and UC3. A summary of intended uses of wood preservatives authorised under PBD and BPR in Poland, sorted under the active substances is included in Appendix I.

Regarding the intended use of *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C,* PL considers that there are many authorised products to be used for protection of wood in UC 3 however only one of them have been authorised as effective against both fungi and insects. The same product is the only one biocidal product in Poland which is intended to be used for protection of wood in use class 4A (situation in which wood or wood product is permanently in contact with the ground). However this product is only intended for treatment of wood by industrial user only by vacuum–pressure method and is not expected to be suitable for substitution of *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C.*

According to “Technical Guidance Note on comparative assessment of biocidal products CA-May” 15-Doc.4.3.a-Final: “in principle, alternative biocidal products requiring a different application method for a given intended use of the relevant biocidal products should still be considered as an alternative. Where a different application method might have an impact on the practical conditions of use of the alternative biocidal product is not a suitable substitute for the relevant biocidal product because of a significant economic or practical disadvantage”.

Regarding above remarks and directions of the guideline, PL CA considers that above mentioned product can not be identified as an alternative biocidal product for *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C.*

So far there are no authorised biocidal products in Poland for protection of wood in UC4B (wood or wood product is permanently in contact with fresh water) and UC 5 (wood constructions in sea water and constructions subject to extreme conditions or where there are special durability and strengths requirements).

Moreover, according to responses submitted to PL CA as a result of public consultation, products for preservation of a wood which are available in Poland do not provide sufficient efficacy for long term service life of sleepers or poles. Therefore, taking into account current situation on Polish market of wood preservation, it can be concluded that products containing creosote are need to be used.

6. Screening phase

In accordance with the guidance document, during the screening phase it shall be checked whether the diversity of the active substance, product type and mode of action combination in authorised biocidal products (BP) is adequate to minimise the occurrence of resistance in the target organisms. Article 23(3)(b) refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two *sine qua non* conditions to be met in order to allow a restriction or prohibition of a BP subject to comparative assessment.

6.1 Chemical diversity of the active substances-mode of action combination in authorised biocidal products in Poland

According to the information available to the PL CA, as of July 2016 the biocidal products authorised under Product Type 8 of the PBD and BPR are based on seven active substances and their combinations. On the basis of information, which are available in Assesment Report for each substance, the modes of action are as presented in Table 6.1:

Table 6.1 Modes of action for PT8 substances in authorised biocidal products

No	Active substances	Mode of action against fungi	Mode of action against insects
1	Tebuconazole	C14-demtehylation inhibitors in sterol biosynthesis	n.a
2	Propiconazole		
3	3-iodo-2-propynylbutylcarbamate (IPBC)	Interferring cell membrane permeability	n.a
4	Cyclohexylhydroxydiazene-1-oxide potassium salt	Inhibition of metabolism	n.a
5	Copper (II) carbonate	(1) non-specifc denaturation of proteins and enzymes (2) interfering with the activity of the pyruvate dehydrogenase system inhibiting the conversion of pyruvate to acetyl CoA within mitochondria (3) reacting with ligands on the cell	Stomach poison

		surface and interfering with membrane function (4) inhibition the production of fungal extracellular enzymes.	
6	Boric acid	Inhibition of metabolism. Primary mode of action is the interaction of the borate anion B(OH)-4 with polyols of biological significance e.g. oxidised co-enzymes (NAD+, NMN+ and NADP+).	Stomach action (disrupts metabolic pathways)
7	Disodium taetraborates		

Regarding the active substance-mode of action combinations in biocidal products, of the active substances listed in Table 6.1, some active substances act against only fungi: tebuconazole, propiconazole, IPBC and cyclohexylhydroxydiazene-1-oxide potassium salt. Only products which contain copper II carbonate are effective against both fungi and insects. If the products containing creosote were removed, only one the biocidal product for PT8 effective against insects, (based on substance- copper II carbonate, propiconazole and tebuconazole) would stay on the market of Poland. Moreover this product is not authorised for the same use as *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C.* According to "Technical Guidance Note on comparative assessment of biocidal products" CA-May 15-Doc.4.3.a-Final: "at least three different and independent "active substances/mode of action" combinations should remain available through authorised BPs for a given use in order to consider that the chemical diversity is adequate. In case of the removing products containing creosote, above mentioned rule will not be fulfilled. Taking into account the available information on the intended use of the biocidal product and the modes of action for PT8 active substances in authorised biocidal products, the PL CA considers that there is no evidence that the chemical diversity of the available active substances is adequate to minimise the occurrence of resistance in the target harmful organisms.

6.2. Conclusion of the screening phase

In line with the “Technical Guidance Note on comparative assessment of biocidal products”, CA-May 15-Doc.4.3.a-Final, where candidate for substitution in the relevant biocidal product is targeted by the exclusion criteria then the interest substitution might prevail and the relevant biocidal product should be subject to a detailed comparative assessment according to Tier I-B whether there is adequate chemical diversity or not. Creosote meets the exclusion criteria listed in Article 5(1) of Regulation 528/2012. However, based on performed mapping of existing alternatives, there is no identified alternative biocidal product.

7. Tier I. Comparison to other alternative biocidal products

Because of the fact that the *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* contain the active substance meeting exclusion criteria listed in Article 5(1) of Regulation 528/2012, in accordance with “Technical Guidance Note on comparative assessment of biocidal products” CA-May 15-Doc.4.3.a-Final the comparative assessment should be continued at Tier I–B. However there is no alternative biocidal product on the Polish market, so step I-B have been omitted.

8. Tier II. Comparison to non-chemical alternatives

In line with “Technical Guidance Note on comparative assessment of biocidal products” CA-May 15-Doc.4.3.a-Final the main goal of Tier II is to conclude whether or not substitution of the relevant biocidal product would be possible by non-chemical method. Eligible non-chemical alternatives are means of control and prevention methods that already exist on the EU market and for which the eCA, on the basis of the available information, considers that there is robust evidence that the alternative:

- has demonstrated sufficient effectiveness under field conditions
- does not present other significant economic or practical disadvantages
- does not give rise to concern in terms of safety for humans, animals or the environment.

Information on non-chemical alternatives are to be collected during the public consultation carried out by ECHA in connection with the approval or renewal of an active substance which is a candidate for substitution, Article 10(3) of the BPR. According to the guidance document on comparative assessment should no further public consultation be required. As creosote was approved as an active substance for use in wood preservative under the BPD a public consultation by ECHA has not been performed. However, as given above under documentation, a stakeholder consultation on creosote, commissioned by the EU Commission, was performed in 2008.

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products has sent the letter to 15 Polish entities (ministries, research units, companies using creosote in its field of activity) with request on existing alternatives, also chemical, for product with creosote on the Polish market. The content of the request of information and the contributions that were received are presented in Appendix II.

Additionally, the applicant was asked for providing an analysis for the technical and economic feasibility of substitution of product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C.* The applicant has submitted an analysis of existing alternatives concerning application of product family with creosote for sleepers and poles for transmission of electric power and telecommunications and the within the agricultural sector. A comprehensive list of documents submitted by the applicants in context of the comparative assessment is given in Appendix III.

A link to the summary of the outcome for the stakeholder consultation on creosote which was performed 2008 initiated by the EU Commission is included in Appendix IV.

8.1 Possible alternative materials to be used for railway sleepers

Non-chemical alternative is mainly focused on a use of plastic, concrete or steel elements in concerned areas. Unfortunately, it is connected with some limitations. While concrete sleepers are used in rail track across most of the EU, wood sleepers are still essential for some parts of a line like crossovers and points where a flexible sleeper is required that can be cut to special sizes. Some of the less frequently used tracks are also carried on wood sleepers. Replacement of wooden sleepers with steel or concrete is recognized as impossible for some applications i.e. power lines located in difficult terrain (forest or mountain). This application presents an alternative, however it is associated with high losses, including environmental.

In some publications where Life Cycle Analysis was carried out, it was shown that in a broader perspective when more environmental aspects are taken into account (e.g. climate, acidification etc), the alternative materials may not be advisable choice when compared to wood treated by creosote.

In the report *LCA of railway sleepers – Comparison of railway sleepers made from concrete, steel, beech wood and oak wood* (Frank Werner, Umwelt & Entwicklung, 2008) life cycle assessment (LCA) and comparison of the environmental impacts of railway sleepers made of concrete, steel, beech wood and oak wood was presented. The environmental effects assessment included influence on terrestrial, freshwater and marine ecotoxicity, human toxicity, photochemical smog, stratospheric ozone depletion, acidification, depletion of abiotic resources and climate change. During the assessment all production steps of the main materials and mounting equipment, over the use phase up to its deconstruction, recycling and final disposal were taken into account. It was concluded that wooden sleepers treated with creosote had the lowest impact on the environment.

8.2 Alternative materials for utility poles to be used for electric power transmission and telecommunication

The authors of document "Comparison of environmental impacts from utility poles of different materials – a life cycle analysis" (Martin Erlandsson, Swedish Environmental Institute (IVL), 2011) presented the comparison of the impacts of wooden poles treated with creosote, concrete poles, steel poles and composite poles (polyester-reinforced fiberglass with a polyethylene coating) on climate change, eutrophication, acidification, ground level ozone, ecotoxicity and human health. According to this paper composite poles have generally similar environmental performance, lower impact on eutrophication and they have greater impact on climate changes in comparison to concrete poles. Creosote poles and concrete poles do not differ so much. Concrete poles contribute more to climate change and eutrophication, while creosote treated wood has a higher impact on photochemical ozone formation and human and ecological toxicity. Steel poles have higher ecotoxicity impact than creosote poles.

8.3 Possible alternative materials to impregnation wood in agricultural sector

In relation to agricultural use of product with creosote, the applicant has submitted several information from end-users. According to submitted information the use of creosote treated stakes in arboriculture is highly required. There are not sufficient alternatives for production of fruits which is very important part of Polish economy e.g. copper products are not economically feasible in comparison to creosote ones. Another important and common field of use of creosote are treated stakes for anti-hail curtains and plastic roofs (coatings). This type of use has also an impact on decreasing the need of use of some pesticides – fruits protected by curtains are also not being frequently wet (by atmospheric conditions) and this also results in restriction of growth of moulds on fruits.

8.4 Possible alternative materials for use impregnation of noise barrier

There were no sufficient information submitted to prove that there are no alternatives for creosote product for impregnation of noise barrier.

8.5 Possible alternative materials for use impregnation of snow barrier

There were no sufficient information submitted to prove that there are no alternatives for creosote product for impregnation of snow barrier.

8.6 Possible alternative materials for use impregnation of horse fences

There were no sufficient information submitted to prove that there are no alternatives for creosote product for impregnation of horse fences.

8.7 Possible alternative materials for use in marine installations

There were no sufficient information submitted to prove that there are no alternatives for creosote product for use in marine installations.

9 Additional information about possible alternatives

Creosote, which is a mixture of hundreds of compounds, contains mainly polycyclic aromatic hydrocarbons ('PAHs'). Some of these have been considered by the Committee for Risk Assessment of the European Chemicals Agency as persistent, bioaccumulative and toxic ('PBT'; anthracene) or very persistent and very bioaccumulative ('vPvB'; fluoranthene, phenanthrene and pyrene). In line with Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto Member States are required to adopt action plans including measures to promote the development and, where they deem appropriate, require the use of substitute or modified materials, products and processes to prevent the formation and release of PAHs.

In connection with it, Polish Chamber of Chemical Industry has submitted information that currently there are conducted studies on the use of mixture of creosote with linseed oil. According to document "Plant oils as "green" substances for wood protection" Nasko Terziev, Dmitri Panov, application of this mixture could decrease the amount of creosote needed for hazard class 3 and 4 to 30% compared to the pure creosote retentions approved today. This might be the only alternative for creosote products but it is not yet available for a commercial use.

10 Overall conclusion of comparative assessment

The alternatives for the applications related to product family *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C*, both chemical and non-chemical do exist on a Polish market. However, there are not fully feasible and possible to apply methods for replacing of creosote-treated wood in relation to applications presented in this report which would have positive impact on socio-economical aspects in comparison with currently used of creosote products/creosote protected wood. Most of potential substitutes of creosote-protected wood are not wildly used, are at the R&D stage or are used for short period of time. In some cases long term experience is needed to finally decide if the alternative is sufficient enough to replace creosote-treated wood – and this information is not available at the time of decision on the authorisation of *Olej kreozotowy gatunek B* and *Olej kreozotowy gatunek C* product family in Poland.

Taking into consideration information and analyses submitted by the applicant and received as a result of public consultations initiated by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products it can be concluded that there are not sufficient alternatives for creosote product in Poland for several uses. Those are:

1) impregnation of wooden sleepers and poles;
2) impregnation in an agricultural sector e.g. fruit tree and hop/vineyard stakes, fences, anti-hail curtains.

Applicant has also requested for authorization of *Olej kreozotowy gatunek B and Olej kreozotowy gatunek C* for impregnation of noise or snow barriers, horse fences and for use in marine installations. Despite above it should be stressed that there was no sufficient information submitted to prove that there are no alternatives for creosote product for impregnation of noise or snow barrier, horse fences and for use in marine installations. Therefore these uses can not be authorized in Poland.

Appendix I. Intended uses of wood preservatives authorized under PBD and BPR in Poland sorted under the active substances.

Active substances in authorized products	Number of products	Aim of application	Target organisms	Use class	Application method
Boric acid	3	preventive	wood rotting basidiomycetes *Serpula lacrymans* wood boring beetles: *Hylotrupes bajalus L.*	1, 2	superficial
Boric acid Disodium Teraborate	2	preventive	wood rotting basidiomycetes wood boring beetles: *Hylotrupes bajalus L.*	1, 2	superficial
	2	preventive	wood rotting basidiomycetes wood boring beetles: *Hylotrupes bajalus L.*	1, 2	superficial, vacuum - pressure
IPBC	4 +1*	preventive	blue stain	2, 3	superficial
	1	preventive	discolouring fungi	2, 3	superficial
	2	preventive	wood rotting fungi blue stain	2, 3	superficial
K-HDO	1	preventive	wood rotting basidiomycetes	2, 3.1	automated and closed system
propiconazole	1	preventive	wood rotting basidiomycetes	2, 3	vacuum-pressure
	1	preventive	discolouring fungi	2, 3	superficial
	1	preventive	discolouring fungi wood rotting fungi	2, 3	superficial double vacuum vacuum-pressure
Propiconazole IPBC	6	preventive preventive/cu	discolouring fungi wood rotting basidiomycetes	2, 3	superficial, insertion

		rative	dry rot fungi		
	3	preventive	discolouring fungi wood rotting basidiomycetes	2, 3	superficial
	4	preventive	wood rotting basidiomycetes blue stain	2, 3	superficial, vacuum - pressure
	4	preventive	wood rotting basidiomycetes blue stain	2, 3	superficial,
	4	preventive	wood rotting fungi blue stain	2, 3	superficial
	6	preventive	wood rotting basidiomycetes blue stain	2, 3	superficial
	5	preventive	blue stain	2, 3	superficial
	6	preventive	wood rotting basidiomycetes blue stain moulds	2, 3	superficial
Tebuconazole IPBC	2	preventive	discolouring fungi wood rotting basidiomycetes	2, 3	superficial
	1	preventive	wood rotting fungi blue stain	2, 3	superficial
Propiconazole Tebuconazole IPBC	3	preventive	wood rotting basidiomycetes blue stain	2, 3	superficial
	1	preventive	wood rotting basidiomycetes blue stain	2, 3	superficial, double vacuum
	1	preventive	blue stain moulds	2, 3	superficial
Propiconazole Tebuconazole Copper II carbonate	1	preventive	wood rotting basidiomycetes wood boring beetles termites	1, 2, 3, 4	vacuum-pressure

*1-the biocidal product family which includes 12 biocidal products

Appendix II. List of the opinions submitted as a result of public consultations initiated by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:

1.	Opinion of The CTL Logistic.
2.	Opinion of The Instytut Chemicznej Przeróbki Węgla.
3.	Opinion of The Infra Silesia.
4.	Opinion of The Jastrzebska Spółka Kolejowa Sp. z o.o.
5.	Opinion of Opinion of The PKP Linia Hutnicza Szerokotorowa Sp. z o.o.
6.	Opinion of The Ministerstwo Infrastruktury i Rozwoju.
7.	Opinion of The TAURON Polska Energia.
8.	Opinion of The TAURON Wytwarzanie.
9.	Opinion of The Polska Izba Przemysłu Chemicznego.
10.	Plant oils as “green” substances for wood protection, ,Nasko Terziev, Dmitri Panov.
11.	Non-Arsenical Wood Protection: Alternatives for CCA, Creosote, and Pentachlorophenol, Freeman M.H.

Appendix III List of the opinions and documents submitted by the Applicant

Table 1. Opinions

1.	Opinion of The PKP Linia Hutnicza Szerokotorowa Sp. z o.o.
2.	Answer for questionnaire about the use of creosote-treated sleepers, The Kopalnia Piasku Kotlarnia – Linie Kolejowe Sp. z o.o.
3.	Answer for questionnaire about the use of creosote-treated sleepers, The PKP Polskie Linie Kolejowe S.A.
4.	Answer for questionnaire about the use of creosote-treated sleepers, The PKP Szybka Kolej Miejska w Trójmieście Sp. z o.o.
5.	Answer for questionnaire about the use of creosote-treated sleepers, The PKP Linie Kolejowe Sp. z o.o.
6.	Opinions of The Nasycalnia Podkładów Sp. z o.o. Pludry.
7.	Opinions of The Nasycalnia Podkładów S.A. Koźmin Wlkp.
8.	Opinion of The Nasycalnia Podkładów w Czeremsze Sp. z o.o.
9.	Opinions of The Track Tec Lipa Sp. z o.o.
10.	Answer for questionnaire about the use of creosote-treated poles, The ENEA Operator Sp. z o.o.
11.	Opinion of The ENERGA Operator Sp. z o.o.
12.	Opinion of The PGE Dystrybucja S.A.
13.	Opinion of The TAURON Dystrybucja S.A. Będzin.
14.	Opinion of The TAURON Dystrybucja S.A. Wałbrzych
15.	Opinion of The Instytut Kolejnictwa
16.	Opinion of The Ministerstwo Gospodarki
17.	Technical and economic analysis the possibility of replacing creosote in Poland for the year 2014, Centrala Obrotu Towarami Masowymi DAW-BYTOM Sp. z o.o.
18.	Answer for questionnaire about the use of creosote in agriculture sector, The Gospodartstwo Sadownicze – Wiesław Mazur.
19.	Answer for questionnaire about the use of creosote in agriculture sector, The Gospodartstwo Sadownicze – Bożena Grzejszczyk
20.	Opinion of The Drewgór S.Walczak i S-ka, Spółka Jawna.

Table 2. Documents:

1.	AqeAeTer, Inc., 2012	Conclusions and Summary Report on an Environmental Life Cycle Assessment of ACQ-Treated Lumber Decking with Comparisons to Wood Plastic Composite Decking, Treated Wood Council,
2.	AqeAeTer, Inc., 2012	Conclusions and Summary Report on an Environmental Life Cycle Assessment of Borate-Treated Lumber Structural Framing with Comparisons to Galvanized Steel Framing, Treated Wood Council
3.	AqeAeTer, Inc., 2013	Life Cycle Assessment Procedures and Findings for Creosote-Treated Railroad Ties
4.	AqeAeTer, Inc., 2013	Conclusions and Summary Report Environmental Life Cycle Assessment of Highway Guard Rail Posts
5.	Treated Wood Council, AqeAeTer, Inc., 2012	Conclusions and Summary Report Environmental Life Cycle Assessment of Marine Pilings
6.	Werner F, 2009	Life cycle assessment (LCA) of railway sleepers. Comparison of railway sleepers made from concrete, steel, beech wood and oak wood,
7.	International Union of Railways (UIC), 2013	SUWOS Sustainable Wooden Railways Sleepers
8.	Kohler et. al, 2000	Inventory and emission factors of creosote, Polycyclic Aromatic hydrocarbons (PAH), and Phenols from Railroad Ties Treated with Creosote
9.	Kohler-Kuenniger, 2003	Emission of PAH from creosoted railroad ties
10.	Erlandsson M., Almemark M., 2009	Background data and assumptions made for an LCA on creosote poles
11.	Coggins C.R., 2013	Technical feasibility of substitution of creosote for the treatment of wood for poles, sleepers, fencing, agricultural uses (including tree stakes), fresh and sea water uses and professional use in the context of application for authorisation of creosote in accordance with the Biocidal Products Directive
12.	Borrie D., 2013	Socio Economic Case for the Continued Use of Creosote as a Wood Preservative for Wood Poles V1.4,
13.	Jaworska A., Milczarek D., Naduk E., 2012.	Impregnation of wooden sleepers with regard to the physicochemical properties of the used products
14.	The Doradca Sadowniczy, 2013	Orchard scaffolding on wooden piles
15.	The Informator Sadowniczy, 2012	Constructions for apple and pear trees
16.	European Institute of wood preservation	BPR – creosote authorisation – comparative assessment

Appendix IV. A summary of the outcome for the stakeholder consultation on creosote which was performed 2008 initiated by the EU Commission; available on website:
http://www.vhn.org/pdf/creosote_report.pdf