NORWEGIAN ENVIRONMENT AGENCY

Koppers international BV
Molenlaan 55
1422XN Uithoorn
The Netherlands

Oslo, 30.03.2017

Your ref.:
[Your ref.]

Our ref. :
2016/3401

Contact person:
Kjetil Haugstad

Authorisation of Creosote BPF Koppers – NO-2017-0128

We refer to your application for mutual recognition of the product family Creosote BPF Koppers, R4BP3 case no. BC-PR024520-31, containing the active substance creosote.

Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 10 April 2014 No. 548. The conditions for granting an approval of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

Creosote as an active substance fulfils two of the exclusion criteria given in Article 5(1) of the BPR. Creosote is classified as carcinogenic in category 1B in accordance with Regulation (EC) 1272/2008 and it contains components which satisfy the criteria in annex XIII of Regulation (EC) no. 1907/2006 and must therefore be considered as persistent, bio-accumulative and toxic (PBT).
The Norwegian Environment Agency has, however, agreed with the reference Member State in that the active substance in the product family, creosote, satisfies the conditions given in Article 5(2) (c), meaning that not authorising products containing this active substance would have disproportionate negative consequences for society in comparison with the risk associated with its use. This imply that the active substance creosote satisfies the criterion given in Article 10(1) (a), and must be viewed as a substance eligible for substitution.
It follows from the transitional measures given in Article 91 of the BPR that a biocidal product must be authorised in accordance with Article 23 of the BPR if the risk assessment of the active substance conclude that one or more of the criteria of Article 10 of the BPR is satisfied. This implies that a comparative assessment which evaluates the availability and quality of alternative biocidal products and non-chemical alternatives, as well as their risks to humans and the environment, must be a part of the product assessment.
The Reference Member State (rMS) has published such a comparative assessment as a part of their product authorisation. The comparative assessment concluded that the availability of alternative biocidal products and non-chemical alternatives currently is insufficient and that not authorising

products with this active substance will result in disproportionate negative consequences for society in comparison with the risk associated with its use. The Norwegian Environment Agency has performed a comparative assessment assessing firstly whether the situation in Norway is comparable to the situation in the rMS. In addition, uses applied for in Norway but not covered by the initial comparative assessment were evaluated. Statements regarding needs and the availability of alternatives from national stakeholders and stakeholder organisations were called for and have been taken into consideration in the decision process.

According to Article 23(6) of the BPR, products containing an active substance that is a candidate for substitution shall only be granted authorisation for a period not exceeding 5 years. To facilitate the renewal procedure in accordance with the Mutual Recognition Renewal Regulation, it is however agreed (CA-Sept14-Doc.5.7 –Final) that authorisations granted by the concerned member states should have the same expiry date as the authorisation which is granted by the reference Member State (rMS).

Decision

Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Creosote BPF Koppers until 29/03/2021.

The following applied uses are authorised:

- Industrial vacuum treatment of wood in use class 3 intended to be used as railway sleepers, for overhead transmission of electricity and telecommunication and for construction of timber bridge structures (timber and glue-laminated wood).
- Industrial vacuum treatment of wood in use class 4 intended to be used for overhead transmission of electricity and telecommunication and glue-laminated wood for timber bridge structures.
- Industrial vacuum treatment of wood in use class 5 intended to be used for marine installations.
- Surface treatment of treated wood after necessary modifications to protect surfaces exposed by such works.

The following applied uses are not authorised:

- Preventive treatment of wood for use in agricultural and equestrian fencing, as well as industrial and highway fencing
- Preventive treatment of wood for use as tree stakes and hop poles in agriculture.
- Timber foundation blocks
- Claddings for houses

According to Article 31(1) of the Biocidal Products Regulation, an application for a renewal of the authorisation must be submitted 550 days before the authorisation period expires, at the latest.

<u>The authorisation concerns:</u>

Product family name:	Creosote BPF Koppers
Products within the family:	WEI B (NO-2017-0128-01)
	WEI C (NO-2017-0128-02)

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Trade name(s):	WEI B
	WEI C
Active substance:	Creosote
Authorisation number:	NO-2017-0128
Authorisation date:	30 /03/2017
Expiry date:	29/03/2021
Product type:	Wood preservatives – PT8
Authorisation holder in Norway:	Koppers International BV

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP3. In some cases a PDF-file of the SPC is automatically generated in R4BP3. In such cases, please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file generally seems to contain some errors.

The authorisation of Creosote products under the BPR is based on the approval of Creosote as an active substance under the BPD. Materials treated with biocides, like Creosote poles, were not regulated under the BPD. The REACH restriction (entry No 31 in Annex XVII to Regulation (EC) No 1907/2006) open up for certain uses of Creosote treated materials, and as long as treated materials for these uses are available on the European market, they can be used for these purposes. This legal situation will not change despite possible restriction now set in national authorisations for the uses of creosote products. However, this situation might change in the future under the BPR as treated materials placed on the market can be regulated, depending on the restrictions set at the substance re-approval. In addition, possible changes in the REACH restriction could in the future restrict further the uses accepted for creosote treated material. The extent of this authorisation has taken into consideration this situation to avoid competition distortion for Norwegian wood treatment industry using Creosote. Any further restriction on uses allowed in this authorization would in practice have limited beneficial effect for human health or environment.

The Norwegian Environment Agency may, in accordance with article 47 of the BPR, cancel or amend the authorisation should new information on the product or the active substance come to our attention that may affect the authorisation. Should the authorisation holder be aware of such information, the Norwegian Environment Agency should be notified without delay.

Label

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the SPC. Furthermore, Article 69(2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above mentioned documents is accurate, and if relevant, translated correctly.

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An electronic copy of the label with the Norwegian authorisation number NO-2017-0128 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Phase-out of products with old labels:
According to Article 52 of the BPR, all products with old labels shall be phased out. This means that products with old labels cannot be made available on the market any longer than 180 days after the authorisation date. The use of existing stocks of the product must cease within 360 days after the authorisation date. During this period, all advertising material related to products with old labels, should also be removed from the market. Any advertising for biocidal products must comply with Article 72 of the BPR and must include the sentences "Use biocides safely. Always read the label and product information before use."

Changes to the authorisation
If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

Yearly fee
For authorised biocidal products, a yearly fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details.

Registration in the Norwegian Product Register
All biocidal products must be registered in the Product Register by using the biocide notification form. In addition, all biocidal products which are classified as hazardous must be fully declared if they are sold in amounts of 100 kg or more per year. Forms and further information can be found at http://miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/

Appeal
This decision can be appealed to the Ministry of Climate and Environment, in accordance with § 7 of the Norwegian Biocide Regulation. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with § 28 of the Norwegian Public Administration Act.

Yours sincerely,
Norwegian Environment Agency

Eli Vike
Head of Section

Kjetil Haugstad
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