EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10842/2021(POOL/E4/2021/10842/10842-EN.doc)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of N,N-diethyl-meta-toluamide for use in biocidal products of product-type 19

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

postponing the expiry date of approval of N,N-diethyl-meta-toluamide for use in biocidal products of product-type 19

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products

Whereas:

(1) The active substance N,N-diethyl-meta-toluamide was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council[2] for use in biocidal products of product-type 19, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) The approval of N,N-diethyl-meta-toluamide for use in biocidal products of product-type 19 will expire on 31 July 2022. On 26 January 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of N,N-diethyl-meta-toluamide.

(3) On 4 June 2021, the evaluating competent authority of France informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency (‘the Agency’) is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

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1 OJ L 167, 27.6.2012, p. 1.

2 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 (OJ L 123, 24.4.1998, p.1).

(6) Consequently, for reasons beyond the control of the applicant, the approval of N,N-diethyl-meta-toluamide for use in biocidal products of product-type 19 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of N,N-diethyl-meta-toluamide for use in biocidal products of product-type 19 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of that approval to 31 January 2025.

(7) Except for the expiry date of approval, N,N-diethyl-meta-toluamide remains approved for use in biocidal products of product-type 19 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of N,N-diethyl-meta-toluamide for use in biocidal products of product-type 19 is postponed to 31 January 2025.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

Done at Brussels,

For the Commission
The President
Ursula Von der Leyen

COMMISSION IMPLEMENTING DECISION (EU) 2021/1839

of 15 October 2021

postponing the expiry date of approval of creosote for use in biocidal products of product-type 8

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) The active substance creosote was included into Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) for use in biocidal products for product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) On 27 October 2016, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of creosote for use in biocidal products for product-type 8.

(3) On 16 September 2019, the former evaluating competent authority of the United Kingdom submitted a recommendation on the renewal to the European Chemicals Agency ('the Agency'). The competent authority of Poland has taken over the role of evaluating competent authority regarding the application on 30 January 2020.

(4) Given that by July 2020 the opinion of the Agency on the renewal of the approval of the active substance was not yet available, the expiry date of approval of creosote has been postponed to 31 October 2021 by Commission Implementing Decision (EU) 2020/1038 ([3]) in order to allow for sufficient time for the completion of the examination of the application.

(5) In accordance with Article 14(3) of Regulation (EU) No 528/2012, the Agency adopted its opinion ([4]) on 4 December 2020, having regard to the conclusions of the evaluating competent authority.

(6) Creosote is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]) and meets the criteria for being a persistent, bioaccumulative and toxic substance and a very persistent and very bioaccumulative substance according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([6]), it meets the exclusion criteria set out in Article 5(1), points (a) and (e) of Regulation (EU) No 528/2012. While the examination to decide whether at least one of

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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 (OJ L 123, 24.4.1998, p. 1).

([3]) Commission Implementing Decision (EU) 2020/1038 of 15 July 2020 postponing the expiry date of approval of creosote for use in biocidal products of product-type 8 (OJ L 227, 16.7.2020, p. 74).

([4]) Biocidal Products Committee (BPC) opinion on the application for renewal of the approval of the active substance: creosote, Product type: 8, ECHA/BPC/274/2020, adopted on 4 December 2020.

([5]) 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 (OJ L 353, 31.12.2008, p. 1).

([6]) 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

the conditions of Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled, and whether the approval of creosote may therefore be renewed, has already started, it will not be possible to complete this examination before the current expiry of approval.

(7) Furthermore, creosote, its compounds and wood treated with them are subject to restrictions laid down in Annex XVII to Regulation (EC) No 1907/2006. Following Commission Implementing Decision (EU) 2019/961 ([7]), France is to submit to the Agency a dossier in accordance with Annex XV to Regulation (EC) No 1907/2006, initiating a Union restrictions procedure in accordance with Articles 69 to 73 of that Regulation. Further examination needs to take place in order to ensure consistency between the assessment of the renewal of the approval of creosote as an active substance under Regulation (EU) No 528/2012 and the Union restriction procedure under Regulation (EC) No 1907/2006, and to provide for an effective control of creosote and wood treated with it.

(8) Consequently, for reasons beyond the control of the applicant, the approval of creosote for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to further postpone the expiry date of approval of creosote for a period of time sufficient to enable the examination of the application.

(9) Considering the period necessary to decide if at least one of the conditions of Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of creosote may therefore be renewed, it is appropriate to postpone the expiry date of approval of creosote to 31 October 2022.

(10) Except for the expiry date of the approval, creosote remains approved subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of creosote for use in biocidal products of product-type 8 is postponed to 31 October 2022.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 15 October 2021.

For the Commission
The President
Ursula VON DER LEYEN

([7]) Commission Implementing Decision (EU) 2019/961 of 7 June 2019 authorising a provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use and the placing on the market of certain wood treated with creosote and other creosote-related substances (OJ L 154, 12.6.2019, p. 44).

EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING DECISION

of XXX

on unresolved objections regarding the terms and conditions of the provisional authorisation of a biocidal product containing 5-Chloro-2-methyl-2H-isothiazol-3-one (C(M)IT) referred by France in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on unresolved objections regarding the terms and conditions of the provisional authorisation of a biocidal product containing 5-Chloro-2-methyl-2H-isothiazol-3-one (C(M)IT) referred by France in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 36(3) thereof,

Whereas:

(1) On 27 July 2018, the company THOR GmbH ('the applicant') submitted an application for mutual recognition in parallel, in accordance with Article 34 of Regulation (EU) No 528/2012, of a provisional authorisation of a biocidal product, as referred to in Article 55(2) of that Regulation, to the competent authorities of a number of Member States, including Germany. The biocidal product concerned is to be used for the preservation of products during storage and contains as an active substance 5-Chloro-2-methyl-2H-isothiazol-3-one (C(M)IT) ('the biocidal product'). France is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany referred objections to the coordination group on 24 January 2020, indicating that the biocidal product is not expected to meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of that Regulation. On 27 January 2020, the coordination group secretariat invited the other Member States and the applicant to submit written comments on the referral. The referral was discussed in the coordination group on 9 and 23 March 2020.

(3) As no agreement was reached by the coordination group, on 11 January 2021 France referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the applicant.

(4) Germany considers that risk-mitigation measures for treated articles can only be included in an authorisation of a biocidal product if they were laid down in the approval decision of the active substance. As C(M)IT is not yet approved as active substance, Germany considers that the risk-mitigation measures for treated articles

[1] OJ L 167, 27.6.2012, p. 1.

proposed by France cannot be included in the authorisation of the biocidal product. Consequently, unacceptable risks remain for use 2 (in-can preservation of paints and coatings), use 3 (preservation of additives used in paper production) and use 7 (preservation of polymer dispersions), described in the application for the provisional authorisation.

(5) Article 19(1), points (b)(iii) and (b) (iv), of Regulation (EU) No 528/2012 provides that one of the conditions for granting an authorisation is that a biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans and animals, and on the environment.

(6) Article 58(2) of Regulation (EU) No 528/2012 provides that a treated article is not to be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2) of that Regulation, for the relevant product-type and use, or in Annex I to that Regulation, and any conditions or restrictions specified therein are met.

(7) Article 55(2) of Regulation (EU) No 528/2012 allows competent authorities to authorise for a period not exceeding three years, a biocidal product containing a new active substance provided that dossiers have been evaluated in accordance with Article 8 of that Regulation, the evaluating competent authority has submitted a recommendation for approval of the new active substance, and the competent authorities which received the application for the provisional authorisation consider that the biocidal product is expected to comply with Article 19(1), points (b), (c) and (d), of that Regulation taking into account the factors set out in Article 19(2) of that Regulation.

(8) Although C(M)IT is not yet approved, the French evaluating competent authority submitted to the European Chemicals Agency on 18 September 2019 a recommendation for approval of C(M)IT for product-type 6. The draft opinion and the assessment report of the evaluating competent authority were discussed at the meeting of the Biocidal Products Committee of 16 June 2020, and unacceptable risks were identified for the aquatic and terrestrial compartment from use 2 (in-can preservation of paints and coatings) and use 7 (preservation of polymer dispersions) of the representative biocidal product and it was concluded that, in the absence of further studies, only a restriction on the use of articles treated with biocidal products containing C(M)IT to indoor uses would lead to acceptable risks. For use 3 of the representative biocidal product (preservation of additives used in paper production), a safe use of treated articles was identified for all the environmental compartments.

(9) The Commission considers that the fact that the conditions or restrictions for treated articles can be included only in the approval decision of the active substance should not prevent the possibility to grant a provisional authorisation of a biocidal product pursuant to Article 55(2) of Regulation (EU) No 528/2012, as that derogation is based precisely on the absence of approval of that active substance and is valid until an active substance is approved and as such provisional authorisation may anticipate future conditions or restrictions for treated articles in the approval decision.

(10) Taking into account all those considerations, the Commission considers that it can be expected that the active substance C(M)IT can be approved and that the approval decision will specify the conditions associated with its use in treated articles, namely a restriction on outdoor use of such articles, and that therefore the biocidal product is expected to meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 provided that, for use 2 (in-can preservation of paints

and coatings) and use 7 (preservation of polymer dispersions), the use of articles treated with the biocidal product is allowed only indoors.

(11) On 25 June 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012.

(12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

This Decision applies to the biocidal product identified by the case number BC-DW041712-25 in the Register for Biocidal Products.

Article 2

The biocidal product referred to in Article 1 of this Decision is expected to meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012, provided that the provisional authorisations granted by Member States stipulate both of the following conditions:

(a) for use 2 (in-can preservation of paints and coatings) and use 7 (preservation of polymer dispersions), as described in the application for the mutual recognition, articles treated with the biocidal product can only be used indoors;

(b) the person responsible for the placing on the market of such treated articles ensure that the label of such treated articles provides the following instruction ‘Indoor use only’.

Article 3

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10906/2021
(POOL/E4/2021/10906/10906-EN.docx
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Konservan P40 in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Konservan P40 in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 36(3) thereof,

Whereas:

(1) On 24 April 2016, the company THOR GmbH ('the applicant') submitted to the competent authorities of several Member States an application for the mutual recognition in parallel of an authorisation for a biocidal product in accordance with Article 34 of Regulation (EU) No 528/2012. The biocidal product concerned, containing permethrin as an active substance, is intended to be used as an insecticide for textiles in the manufacturing of clothing and for non-washable wool used in the manufacturing of carpets ('the biocidal product'). France is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) On 1 August 2019, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Belgium referred objections to the coordination group set up pursuant to Article 35(1) of that Regulation, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b)(iii), of that Regulation. On 5 August 2019, the coordination group secretariat invited the other Member States and the applicant to submit written comments on the referral. The referral was discussed in the coordination group on 16 and 26 September 2019.

(3) Belgium considered that the migration rate for permethrin used by France in the human health exposure assessment was not adequate. According to Belgium, the migration rate should have been 1 % as agreed in the assessment report established in the context of the approval of permethrin[2] instead of 0,1 % used by France. Following the discussions that took place in the coordination group, France proposed to use the dermal absorption value of 3 % as agreed in the assessment report established in the context of the approval of permethrin while Belgium considered that the value was not adequate and that the 75 % default value specified in the European Food Safety Authority (EFSA) Guidance should be used instead.

[1] OJ L 167, 27.6.2012, p. 1.

[2] https://echa.europa.eu/documents/10162/49872cf9-4c65-ce75-2230-d7d8befef7ab

(4) As no agreement was reached in the coordination group, on 28 October 2019 France referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and the applicant.

(5) On 4 March 2021, the Commission requested an opinion on that matter from the European Chemicals Agency ('ECHA') in accordance with Article 36(1) and Article 38 of Regulation (EU) No 528/2012. ECHA was requested to indicate which migration rate and dermal absorption value should be used in the human health exposure assessment for the different uses envisaged of the articles treated with the biocidal product, and whether using those values allows to conclude that the biocidal product has no unacceptable effects on the health of humans.

(6) On 17 June 2021, the Biocidal Products Committee of the Agency adopted its opinion[3].

(7) According to ECHA, the appropriate migration rate for clothes treated with permethrin is 1 %, while for wool carpets treated with permethrin it is 0,5 %. For the dermal absorption of permethrin, the adequate value is the default value of 50 % recommended by EFSA for water-based products[4].

(8) According to ECHA, the conditions of Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are met for the use of the biocidal product in wool carpets, while for use in clothing, those conditions are met if the biocidal product is not used for manufacturing of clothing intended for the general public.

(9) Therefore, in light of the opinion of ECHA, the Commission considers that the biocidal product meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 if the biocidal product is not used for manufacturing of clothing intended for the general public.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by case number BC-SH023802-41 in the Register for Biocidal Products meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the authorisations granted by Member States stipulate the condition that the biocidal product shall not be used for manufacturing of clothing intended for use by the general public.

Article 2

This Decision is addressed to the Member States.

[3] https://echa.europa.eu/bpc-opinions-on-article-38

[4] Guidance on dermal absorption (wiley.com)

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission

EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding terms and conditions of the authorisation of the biocidal product family Oxybio in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding terms and conditions of the authorisation of the biocidal product family Oxybio in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 36(3) thereof,

Whereas:

(1) On 26 July 2018, the company Intergaz et Services ('the applicant') submitted an application to the competent authorities of a number of Member States, including France, for mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product family Oxybio of surface disinfectant products containing the active substance hydrogen peroxide in concentrations between 12 and 49% weight for weight ('the biocidal product family'). Belgium is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) The biocidal product family comprises products containing hydrogen peroxide in concentrations of 12%, 30%, 35% and 49%, organised in three sub-families, the technical properties of which are described in three summaries of biocidal product characteristics (meta SPCs), namely meta SPC 1, meta SPC 2 and meta SPC 3. In its assessment report Belgium recommended authorisation only for those products of the biocidal products family which contain hydrogen peroxide in a concentration of 12%. Those products are covered by meta SPC 1 (Oxybio L12).

(3) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group on 29 September 2020, indicating that the contested product family does not meet the conditions laid down in Article 19(1), point (d), of that Regulation.

(4) France considered that the determination of the physical hazards of the products in the biocidal product family made by Belgium with regard to the oxidising liquids property, and indicated in the draft summary of the biocidal product characteristics (SPC) pursuant to Article 22(2), point (i), of Regulation (EU) No 528/2012, was not correct. Belgium indicated that specific concentration limits of hydrogen peroxide, as set out in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the

[1] OJ L 167, 27.6.2012, p. 1.

European Parliament and of the Council[2], had been considered for the determination of oxidising property of the biocidal product family and that the lower limit, namely 50%, was not met by any of the products of the biocidal product family. Hence, Belgium concluded that the products were not to be classified in relation to this property.

(5) France argued that not classifying the products in relation to the oxidising liquids property is incorrect. France maintained that, as indicated in the Guidance on the Application of the CLP criteria[3] of the European Chemicals Agency ('ECHA Guidance'), the experience in the handling and use of substances or mixtures which shows them to be oxidising is an important factor in considering classification in this hazard class. According to France, the application of the UN Model Regulations on the Transport of Dangerous Goods (UN RTDG Model Regulations) represents such experience and the classification according to these Regulations should be included in the draft SPC. Consequently, France concluded that the correct classification of the products of the biocidal product family covered by the meta SPC 1 (Oxybio L12) should be Oxidising liquid, Packing group III, as set out in the UN RTDG Model Regulations.

(6) As no agreement was reached in the coordination group, on 10 December 2020 Belgium referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. Belgium provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. A copy of that statement was forwarded to the Member States concerned and the applicant.

(7) Article 19(1), point (d), of Regulation (EU) No 528/2012, lays down one of the conditions for granting an authorisation, namely that the physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product.

(8) Point 2.13.2.1 of Annex I to Regulation (EC) No 1272/2008 provides that an oxidising liquid is to be classified in one of the three categories for this class (Category 1, 2 or 3) using test O.2 in Part III, sub-section 34.4.2 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, in accordance with the criteria laid down in Table 2.13.1 of that Annex.

(9) Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 provides in the entry with index number 008-003-00-9 the harmonised classification for hydrogen peroxide solutions in relation to the oxidising liquids property with specific concentration limits, as follows: Oxidising Liquid Category 1 with not less than 70% hydrogen peroxide and Oxidising Liquid Category 2 with not less than 50% but no more than 70% hydrogen peroxide. However, four asterisks '(****)' accompany those limits, indicating that the correct classification is to be confirmed by testing, as laid down in point 1.2.4 of Part 1 of Annex VI to that Regulation.

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2 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 (OJ L 353, 31.12.2008, p. 1).

3 ECHA Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0, July 2017 https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5.

(10) The applicant did not provide any test data in relation to the oxidising liquids property. The applicant considered that the specific concentration limits indicated in Table 3 of Part 3 of Annex VI, to Regulation (EC) No 1272/2008, in the entry with index number 008-003-00-9, were applicable for the classification in relation to the oxidising liquids property and that their application led to the non-classification of the products of the biocidal product family in relation to this property.

(11) In accordance with the UN RTDG Model Regulations, aqueous solutions with more than 8% hydrogen peroxide should be classified in division 5.1 (oxidising substances) as follows: Oxidising liquid, Packing group III, with not less than 8% but not more than 20% hydrogen peroxide; Oxidising liquid, Packing group II, with not less than 20% but not more than 60% hydrogen peroxide; Oxidising liquid, Packing group I, with more than 60% hydrogen peroxide. The classification in relation to this hazard class is based on the same test as the one required by point 2.13 of Part 2 of Annex I to Regulation (EC) No 1272/2008.

(12) As provided in section 2.13.5 of the ECHA Guidance, Packing group I, II and III as defined under the UN RTDG Model Regulations for Oxidising liquids correspond directly to Category 1, 2 and 3 for Oxidising liquids, respectively, of Regulation (EC) No 1272/2008.

(13) Pursuant to point 2.13.4.3 of Part 2 of Annex I to Regulation (EC) No 1272/2008, in the event of divergence between test results and known experience, judgement based on known experience is to take precedence over test results. Corresponding section 2.13.4.3 of the ECHA guidance also indicates that, apart from testing, also experience in the handling and use of substances or mixtures, which shows them to be oxidising, is an important additional factor in considering classification in this hazard class.

(14) For the carriage of dangerous goods within and between the territories of the Member States, Article 3 of Directive 2008/68/EC of the European Parliament and of the Council[4] imposes the application of Annexes A and B of the European Agreement concerning the International Carriage of Dangerous Goods by Road ('ADR'), of the Annexed Regulations to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways ('ADN'), as well as Articles 3(f), 3(h), 8(1) and 8(3) of the ADN, and of the Annex to the Regulations concerning the International Carriage of Dangerous Goods by Rail ('RID').

(15) The ADR, ADN and RID are following the UN RTDG Model Regulations and contain the classification of aqueous solutions containing hydrogen peroxide as set out by the UN RTDG Model Regulations. For the purposes of transportation, the products of the biocidal product family covered by meta SPC 1 are therefore to be classified as Oxidising liquid, Packing group III in accordance with ADR, ADN and RID.

(16) In the absence of test data provided by the applicant it seems appropriate to apply judgement based on known experience in the handling and use of aqueous solutions containing hydrogen peroxide concerning the classification in relation to the oxidising liquids property. In this context, the legislation on the carriage of dangerous goods provides binding criteria on the classification of substances and mixtures, including in relation to oxidising liquids hazard class, that are relevant for the case at hand.

[4] Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

(17) It is therefore appropriate to indicate in the draft SPC that products containing hydrogen peroxide in a concentration of 12% are to be classified as Oxidising liquid, Packing group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category 3, in accordance with Regulation (EC) No 1272/2008.

(18) On 8 April 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant provided comments which the Commission, subsequently, took into account.

(19) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

This Decision applies to the products covered by meta SPC 1 (Oxybio L12) of the biocidal product family identified by the case number BC-SK041671-32 in the Register for Biocidal Products.

Article 2

For the purpose of Article 19(1), point (d), of Regulation (EU) No 528/2012, the hazard classification with regard to the oxidising liquids property of the products referred to in Article 1, shall be Oxidising liquid, Packing group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category 3, in accordance with Regulation (EC) No 1272/2008.

The products referred to in Article 1 meet the condition laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012 provided that they are classified as Oxidising liquid, Packing group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category 3, in accordance with Regulation (EC) No 1272/2008.

Article 3

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10742/2021
(POOL/E4/2021/10742/10742-EN.docx)
[…](2021) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Teknol Aqua 1411-01 in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of XXX

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Teknol Aqua 1411-01 in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 36(3) thereof,

Whereas:

(1) On 14 September 2018, the company Teknos A/S ('the applicant') submitted to the competent authorities of several Member States, including Germany, an application for mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Teknol Aqua 1411-01, containing the active substances 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (propiconazole) and 3-iodo-2-propynyl butyl carbamate (IPBC) ('the biocidal product'). The biocidal product is intended to be used for preservation of wood used indoor (use class 2[2]) and for preservation of wood used outdoors not in contact with the ground (use class 3[2]) . Denmark is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) The biocidal product contains very low concentrations of three non-active substances which are residual monomers of the silicon emulsion added as anti-foaming agent during the production process: octamethylcyclotetrasiloxane (D4) in concentration of 0,000024% weight by weight (w/w), decamethylcyclopentasiloxane (D5) in concentration of 0,000054% (w/w) and dodecamethylcyclohexasiloxane (D6) in concentration of 0,00008% (w/w). D4, D5 and D6 have been identified[3] as persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[4].

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1 OJ L 167, 27.6.2012, p. 1.

2 The use classes are defined in the European standard CSN EN 335 - Durability of wood and wood-based products - Use classes: definitions, application to solid wood and wood-based products.

3 ECHA Decision ED/61/2018: https://echa.europa.eu/documents/10162/61ac8d81-6ea2-6ad0-ffef-95037c9182ce

4 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council

(3) On 5 November 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany referred objections to the coordination group, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b) (iv), of that Regulation for use class 3. The referral was discussed in the coordination group on 25 November 2020.

(4) As no agreement was reached in the coordination group, on 5 January 2021 Denmark referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. Denmark provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. The statement was forwarded to the Member States concerned and to the applicant.

(5) Germany considers that the application of point 48 of Annex VI to Regulation (EU) No 528/2012 should lead the evaluating body to conclude that the biocidal product does not meet the condition laid down in Article 19(1), point (b)(iv), of that Regulation. Point 48 of Annex VI to Regulation (EU) No 528/2012 indicates that the evaluating body is to conclude that the biocidal product does not comply with criterion laid down in Article 19(1), point (b)(iv), of that Regulation if the biocidal product contains any substance of concern fulfilling the criteria for having PBT or vPvB properties in accordance with Annex XIII to Regulation (EC) No 1907/2006, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. Germany considers that D4, D5 and D6 are substances of concern as defined in Article 3(1), point (f), of Regulation (EU) No 528/2012 and that, since for PBT and vPvB substances no safe threshold value can be derived below which the release to the environment can be considered acceptable, any release of these substances to the environment is to be considered as having an unacceptable effect. Consequently, Germany argues that since a partial leaching of the biocidal product in the environment is expected due to the weathering of the wood as regards the use class 3, that use should not be authorised.

(6) Denmark argues that since the concentrations of D4, D5 and D6 in the biocidal product are very low (combined concentration of all three of them is 0,000158% (w/w)), their presence in the product does not result in unacceptable effects on the environment. Moreover, according to the information provided by the applicant, currently there are no appropriate alternatives to the anti-foaming agent containing these impurities for the production of the biocidal product.

(7) Article 56(1) and (2) of Regulation (EC) No 1907/2006 sets out the authorisation requirement for substances included in Annex XIV to that Regulation. Annex XIV to Regulation (EC) No 1907/2006 includes also substances which are PBT and vPvB. However, Article 56(6) of that Regulation establishes that the authorisation requirement does not apply to substances identified as PBT or vPvB when those substances are present in mixtures in concentration below 0,1% (w/w).

(8) Furthermore, the Guidance on Regulation (EC) No 1907/2006, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment[5] of the European Chemicals Agency, provides that constituents, impurities

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Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

[5] Version 3.0 of June 2017 https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of at least 0,1% (w/w). According to that guidance document, the limit of 0,1% (w/w) is based on a well-established practice recognised in Union legislation to use this limit as a generic limit. In the same guidance document it is also noted that this threshold value may be elevated or reduced on a case-by-case basis.

(9) The Guidance on the Biocidal Products Regulation, Volume V, Guidance on applications for technical equivalence[6] of the European Chemicals Agency provides that PBT and/or vPvB properties of impurities are normally assessed when the impurities are present in concentration of at least 0,1% (w/w), and only above that threshold value the impact of the PBT and/or vPvB properties of the impurities is considered.

(10) It follows that a concentration limit of 0,1% (w/w) is applied for the purpose of technical equivalence assessment with regard to PBT and/or vPvB properties of impurities under Regulation (EU) No 528/2012 and for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006.

(11) Article 3(1), point (f), of Regulation (EU) No 528/2012 provides a definition of a substance of concern, stating in particular that the substance is present or is produced in a biocidal product in sufficient concentration to present risks.

(12) As set out in a note for guidance[7] presented to the competent authorities of the Member States for the implementation of Regulation (EU) No 528/2021 in June 2021, the Commission considers that, for reasons of coherence with the approach followed for the technical equivalence assessment with regard to PBT and/or vPvB properties of impurities under Regulation (EU) No 528/2012 and for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006, the same concentration limit of 0,1% (w/w) should be applied to determine whether a substance identified as having PBT and/or vPvB properties in accordance with Annex XIII to Regulation (EC) No 1907/2006 and contained in a biocidal product, is a substance of concern. This implies that a substance identified as having PBT and/or vPvB properties and contained in a biocidal product should be considered as substance of concern if its concentration is higher than or equal to 0,1% (w/w) in the biocidal product. Where the biocidal product contains multiple substances identified as having PBT and/or vPvB properties in individual amounts of less than 0,1% (w/w), the concentration limit should be considered to apply for the group of substances. The competent authorities agreed with the Commission's position.

(13) The total concentration of D4, D5 and D6 in the biocidal product is considerably lower than 0,1% (w/w). Those non-active substances should therefore not be considered as substances of concern for the assessment of the biocidal product. As the substances D4, D5 and D6 are neither substances of concern, nor relevant metabolites, breakdown or reaction products, point 48 of Annex VI to Regulation (EU) No 528/2012 does not

[6] Version 2.0 of July 2018 https://echa.europa.eu/documents/10162/2324906/guidance_applications_technical_equivalence_en.pdf/18f72d37-98b6-47c8-98bb-941afeff6968

[7] Draft note for agreement by Member States' Competent Authorities for biocidal products. Categorisation of a biocidal product containing a non-active substance meeting the criteria for being PBT or vPvB (CA-June21-Doc.4.3_final), https://circabc.europa.eu/w/browse/534d6f76-bbfd-432b-b99b-d567d7f827f1

apply as regards the evaluation of the biocidal product in relation to the presence of those substances.

(14) On 9 August 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant provided comments which the Commission, subsequently, has taken into account.

(15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

This Decision applies to the biocidal product identified by the case number BC-FB042589-47 in the Register for Biocidal Products.

Article 2

The presence of the non-active substances octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in a total concentration lower than 0,1% (w/w) in the biocidal product referred to in Article 1 does not imply that the biocidal product has unacceptable effects on the environment within the meaning of Article 19(1), point (b)(iv) of Regulation (EU) No 528/2012.

Article 3

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission