

**Recommendation of the European Chemicals Agency
of 6 February 2014
for the inclusion of substances in Annex XIV to REACH
(List of Substances subject to Authorisation)**

The European Chemicals Agency,

Having regard to 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 (the REACH Regulation), establishing a European Chemicals Agency (ECHA), 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/EC¹, and in particular Article 58 thereof,

Having regard to the Candidate List of Substances of Very High Concern for authorisation, as last amended by Decision ED/169/2012²,

Having regard to the opinion of ECHA's Member State Committee of 12 December 2013³,

Whereas:

- (1) This Recommendation aims to assist the Commission in taking its decision pursuant to Article 58(1) of the REACH Regulation to include substances referred to in Article 57 in Annex XIV to the REACH Regulation.
- (2) Pursuant to Article 58(3) of the REACH Regulation, ECHA is required to make further recommendations of priority substances at least every second year with a view to including further substances in Annex XIV.
- (3) In accordance with Article 58(4) of the REACH Regulation, ECHA published on its website on 24 June 2013 a draft Recommendation of substances to be included in Annex XIV and invited all interested parties to submit comments by 23 September 2013. ECHA has analysed and prepared responses to comments received and will make these publicly available⁴.

¹ OJ L 396, 30.12.2006, p 1

² <http://echa.europa.eu/web/guest/candidate-list-table>

³ http://echa.europa.eu/documents/10162/13576/opinion_draft_recommendation_annex_xiv_fifth_en.pdf

⁴ See links to responses to comments (RCOM) documents:
<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

- (4) Using the approach developed to support the prioritisation of substances for inclusion in Annex XIV pursuant to Article 58(3) of the REACH Regulation⁵ ECHA has prioritised the following five substances from the Candidate List⁶:

#	Substance name	EC
1	N,N-dimethylformamide (DMF)	200-679-5
2	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)	204-650-8
3	Aluminosilicate Refractory Ceramic Fibres (Al-RCF) <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+MgO+BaO) content less or equal to 18% by weight</i>	-
4	Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+MgO+BaO) content less or equal to 18% by weight</i>	-
5	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) <i>[covering well-defined substances and UVCB substances, polymers and homologues]</i>	-

- (5) ECHA is required by Article 58(1) of the REACH Regulation to recommend for each priority substance an Annex XIV entry specifying: its identity; its intrinsic properties referred to in Article 57; the date(s) referred to in Article 58(1)(c)(ii) of the REACH Regulation by which an application should be received if the applicant wishes to continue to use the substance or place the substance on the market ("latest application date"); the date referred to in Article 58(1)(c)(i) of the REACH Regulation from which the placing of the market and use of a substance is prohibited unless an authorisation is granted ("sunset date"); the review periods for certain uses, if appropriate; and uses or categories of uses to be exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.
- (6) Using the approach developed to support determining the Annex XIV entries of prioritised substance⁷ ECHA has determined the specific Annex XIV entries for each of the above listed substances.
- (7) In order to identify the substances pursuant to Article 58(1)(a) of the REACH Regulation ECHA provides the names of the substances and, where applicable, their EC numbers and CAS numbers.

⁵ http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf

⁶ http://echa.europa.eu/documents/10162/13640/prioritisation_results_5th_rec_en.pdf

⁷ http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_5th_en.pdf

- (8) For the transitional arrangements referred to in Article 58(1)(c) of the REACH Regulation, ECHA has applied for each substance a standard time period of 18 months between the suggested latest application date and the sunset date because neither the available information for the recommended substances nor the comments received during public consultation provide information that would support the recommendation of longer periods.
- (9) The recommended latest application dates are based on the assumption that the substances listed in this Recommendation will be included in Annex XIV in February 2015⁸. The latest application dates have been set having regard to ECHA's capacity to handle applications in the time provided for, in accordance with Art. 58(3) of the REACH Regulation, over a period of 6 months (18, 21 or 24 months from entry into force) to distribute the workload in the authorisation application and decision phase more evenly.
- (10) The information available for the recommended substances, including the comments received during the public consultation, which took place from 24 June to 23 September 2013, does not provide information that would justify for the upfront definition of review periods for any uses of the substances in accordance with Article 58(1)(d) of the REACH Regulation.
- (11) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific EU legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.
- (12) ECHA has received during the public consultation, which took place from 24 June to 23 September 2013, comments requesting exemptions of uses. Based on its assessment of these exemption requests⁹, ECHA does not recommend any exemptions from the authorisation requirement on the basis of Article 58(1)(e) and Article 58(2) of the REACH Regulation.
- (13) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development (PPORD). The information available for the recommended substances, including the comments received during public consultation, does not provide grounds to recommend exemptions from the authorisation requirement for PPORD on the basis of Article 56(3) of the REACH Regulation.

⁸ In case the amendment of Annex XIV will not enter into force in February 2015, the latest application dates may need to be adapted in order to fit with the application submission windows (i.e. with their end dates) as communicated on ECHA's website (<http://echa.europa.eu/web/guest/applying-for-authorisation/submission-windows>).

⁹ See links to responses to comments (RCOM) documents: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

HEREBY RECOMMENDS that for the reasons set out in Annex I to this Recommendation, the following entries are included in Annex XIV to the REACH Regulation (List of Substances subject to Authorisation)

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties*	Latest application date pursuant to REACH Art. 58 (1) (c) (ii)	Sunset date	Review periods	Exempted uses or categories of uses	Exemptions for PPORD
1	N,N-dimethylformamide (DMF)	200-679-5	68-12-2	Art. 57 (c); Toxic for Reproduction 1B	Date of inclusion in Annex XIV plus 18 months ¹⁾	Latest application date plus 18 months	None	None	None
2	Diazeno-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)	204-650-8	123-77-3	Art. 57 (f); Equivalent level of concern having probable serious effects to human health	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
3	Aluminosilicate Refractory Ceramic Fibres (Al-RCF) <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+MgO+BaO) content less or equal to 18% by</i>	-	-	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None

Draft Annex XIV entries									
#	Substance	EC number	CAS Number	SVHC-relevant intrinsic properties*	Latest application date pursuant to REACH Art. 58 (1) (c) (ii)	Sunset date	Review periods	Exempted uses or categories of uses	Exemptions for PPORD
4	Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight</i>	-	-	Art. 57 (a); Carcinogen 1B	Date of inclusion in Annex XIV plus 21 months ²⁾	Latest application date plus 18 months	None	None	None
5	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated <i>[covering well-defined substances and UVCB substances, polymers and homologues]</i>	-	-	Art. 57 (f); Equivalent level of concern having probable serious effects to the environment	Date of inclusion in Annex XIV plus 24 months ³⁾	Latest application date plus 18 months	None	None	None

* Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances*) of 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.

- 1) Assuming the Commission Regulation including the substances of this fifth Recommendation in Annex XIV would enter into force in February 2015, the latest application date would be August 2016
- 2) Assuming the Commission Regulation including the substances of this fifth Recommendation in Annex XIV would enter into force in February 2015, the latest application date would be November 2016
- 3) Assuming the Commission Regulation including the substances of this fifth Recommendation in Annex XIV would enter into force in February 2015, the latest application date would be February 2017

Done at Helsinki, 6 February 2014

For the European Chemicals Agency,



Geert Dancet
Executive Director

ANNEX I - Reasons for the recommendation to include the prioritised substances in Annex XIV

Introduction:

The purpose of this Annex is to describe the reasons for recommending the following five substances for inclusion in Annex XIV and the determination of their draft Annex XIV entries.

1. N,N-dimethylformamide (DMF)
2. Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)
3. Aluminosilicate Refractory Ceramic Fibres (Al-RCF)¹
4. Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)²
5. 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)³

For the preparation of this Recommendation ECHA has used the following documents:

- *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation (28 May 2010)*⁴
- *Draft results of the 5th prioritisation of the SVHCs on the Candidate List with the objective to recommend priority substances for inclusion in Annex XIV (24 June 2013, revised 5 July 2013 with regard to decaBDE)*⁵
- *Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach (24 June 2013)*⁶
- Substance-specific background documents (6 February 2014)⁷

¹ The full name of this Candidate List entry is: "Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+MgO+BaO) content less or equal to 18% by weight"

² The full name of this Candidate List entry is: "Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+MgO+BaO) content less or equal to 18% by weight"

³ The full name of this Candidate List entry is: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]

⁴ http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf

⁵ http://echa.europa.eu/documents/10162/13640/prioritisation_results_5th_rec_en.pdf

⁶ http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_5th_en.pdf

- Substance specific “*Responses to comments*” (RCOM) documents (6 February 2014)⁸
- Opinion of the Member State Committee on the fifth draft recommendation of the priority substances and Annex XIV entries (Adopted on 12 December 2013)⁹

The substance specific sections 1 to 5 below provide i) a summary of the reasons for prioritising the substance including ECHA’s reflection on the main issues brought up in the MSC opinion and ii) a summary of the reasons for defining the Annex XIV entries.

⁷ See link to substance-specific background documents at the 5th recommendation webpage:
<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

⁸ See link to responses to comments (RCOM) documents at the 5th recommendation webpage:
<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

⁹ http://echa.europa.eu/documents/10162/13576/opinion_draft_recommendation_annex_xiv_fifth_en.pdf

1. N,N-dimethylformamide (DMF)

1.1 Reasons for prioritising N,N-dimethylformamide (DMF)

DMF is used in very high volumes in the scope of authorisation. The use of the substance is expected to take place at a high number of sites. For some operations significant potential for workers exposure cannot be excluded.^{10,11}

DMF received high priority among the substances on the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Notes to MSC views

The MSC opinion notes that also other polar aprotic solvents than DMF, namely DMAC and NMP, are currently considered for potential further regulatory action under the REACH Regulation. ECHA agrees with the view expressed in the MSC opinion that it is not appropriate for ECHA to assess the pertinence of other regulatory risk management instruments in the Annex XIV recommendation, which is one step in the authorisation process. Considering that DMAC is included in ECHA's 4th Annex XIV recommendation and given that the outcome of the ongoing restriction process for NMP is not known, ECHA has included DMF in this 5th recommendation to enable a consistent approach.

1.2 Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name:	N,N-Dimethylformamide (DMF)
EC Number:	200-679-5
CAS Number:	68-12-2

2) Intrinsic properties of the substance

N,N-Dimethylformamide (DMF) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction, Repr. 1B, H360D ("May damage the unborn child"), and was therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

3) Transitional arrangements

¹⁰ The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

¹¹ The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on DMF does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

During the public consultation comments on transitional arrangements were received. Apart from one comment appearing to request shortening the transitional arrangements, the comments mostly referred to extending the transitional arrangements based on arguments that more time is needed for developing and implementing alternatives (e.g. adaption/redesigning/re-validation of processes and products) or for continuing use of products with long service life. There was also reference to some cases where parallel applications may need to be prepared, as more than one substances recommended for inclusion in Annex XIV are used in the production of the same (In Vitro Diagnostic) products. Requested time periods ranged from having a sunset date (SSD) of 7 up to ~50 years after inclusion. ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards is information which should be included in an eventual application for authorisation. Further details can be found in the '*Response to Comments Document for DMF*'.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Latest application date:*
Date of inclusion in Annex XIV plus 18 months
- *Sunset date:*
18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for uses of DMF in In Vitro Diagnostics, of 7-10 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the '*Response to Comments Document for DMF*'.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of DMF.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of DMF on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions but also a number of requests for exemptions of DMF, for specific uses or broader spectrum of uses (e.g. covered by certain legislation). Several requests referred to existing EU legislation, while there were also requests based on other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of DMF. Finally, it is also noted that some of the uses requested exemptions may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the '*Response to Comments Document for DMF*'.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of DMF on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) Application of authorisation to product and process oriented research and development (PPORD)

ECHA received and assessed requests for exemption of DMF from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. These requests mainly referred to PPORD activities for the production of diagnostic or medicinal/veterinary products and in most cases asked for volumes up to 10 t/y or 50 t/y to be exempted, respectively.

ECHA considers that in accordance with Article 55 of REACH one of the aims of Authorisation is progressive replacement of SVHCs where this is technically and economically viable. Therefore, any further PPORD activities which may require the use of a substance included in Annex XIV should in principle aim at developing alternative substances and technologies to replace the SVHC in question or to further develop processes to improve the control of risks until feasible alternatives are available. However, ECHA notes that actors can apply for a use of a substance (included in Annex XIV) for any PPORD activity and the pertinence of a PPORD activity with a substance identified as SVHC should be justified in an authorisation application and be scrutinized and decided in the authorisation granting process in accordance with Article 60.

In conclusion, ECHA could not find grounds to recommend exempting the use of DMF for PPORD from authorisation.

2. Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)

2.1 Reasons for prioritising Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)

ADCA is used in very high volumes in the scope of authorisation. The use is expected to take place at a high number of sites, in applications where potentially significant exposure of workers cannot be excluded.^{12,13}

ADCA received high priority among the substances on the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Notes to MSC views

The majority of the MSC agreed to the prioritisation of ADCA, however, eight MSC members provided a minority position expressing some concerns on its recommendation for inclusion to Annex XIV. The arguments brought forward in the minority position relate to the form in which the substance is used, the views on the general control of risks on sites, the types of actors involved in its supply chain, and the appropriateness of authorisation as a risk management instrument. ECHA notes that no new data, i.e. data which ECHA had not already taken into account when prioritising the substances and drafting its recommendation and which would be relevant for the prioritisation in accordance with Article 58(3) of the REACH Regulation, has been presented during the MSC opinion forming or in the minority position.

Firstly, it is claimed in the minority opinion that, as ADCA is a respiratory sensitiser, when evaluating its priority, the assessment of the tonnage used and number of sites should take into account only powder forms, since these would have the greatest potential for inhalation. ECHA notes that, according to the agreed prioritisation approach, the volume of the substance which is used in applications in the scope of authorisation should be considered (and has been considered for all substances in the Candidate List assessed for their priority). The harmonised classification of ADCA (which was the basis for its identification as SVHC) applies to all its forms, and therefore all forms should be taken into account when assessing the volume criterion. In any case, since almost the complete volume is imported in powder form and used as such at least at one life cycle stage, the conclusion for this priority criterion would not change if only powder forms would be considered.

Processes, in which potential for significant exposure cannot be excluded, have been identified in formulation, compounding, and conversion steps of the life cycle of ADCA, based on data in (updated) registrations and from the public consultations. Following the prioritisation approach, for assessing the wide

¹² The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

¹³ The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

dispersiveness of the substance, the respective “release potential” score has been multiplied by the score for the “number of sites” in the scope of authorisation, which according to the information provided by industry count in hundreds. ECHA acknowledges that for ADCA the SVHC property relates to inhalation exposure, and that use in forms of negligible fugacity may, under certain conditions, make it less likely that significant exposure levels arise. However, it is emphasized that:

- powder forms are not only used in the formulation stage; survey data provided by industry during public consultation show that various forms are supplied on the market, with powders used by many of the ADCA users, including also several compounders and converters
- not only the pure powder form, but also pre-blended powders and powder pre-mixes are forms which would be expected to lead to significant air concentrations; already these forms seem to occur at around 100 sites based on estimates provided in public consultation
- there is a large variety of forms supplied on the market and it is difficult (in particular at this stage of the authorisation process) to conclude that certain categories of forms would by default entail negligible exposure potential. For instance, there is a difference between “dust-free” and “low-dust” forms as for the latter significant exposure levels cannot be excluded – especially as for ADCA there are indications that it can cause effects already at low exposure levels. Furthermore, forms such as liquid dispersions may form liquid aerosols and may as well lead to significant exposure.

In conclusion, based on the prioritisation approach, ECHA considers that the score assigned for the “number of sites” is justified and fully in line with the information available for this substance.

The minority opinion claims that the release of ADCA is generally controlled at the companies’ sites and suggests that this should be taken into account in the prioritisation. The prioritisation is carried out to support the decision in which order substances in the Candidate List are included in Annex XIV. ECHA considers that the assessment of the level of control or level of exposure is not appropriate during this phase of the authorisation process since it would shift the burden of proof back to authorities. ECHA notes that, would this substance be included in the authorisation list, such an assessment of exposure will be carried out by applicants for the uses they apply for as part of their authorisation application. This assessment is considered by the Risk Assessment and Socio-economic Analysis Committees when forming their opinions and by the Commission when deciding on whether the authorisation is granted.

ECHA further considers that the assessment of the level of control or level of exposure is not necessary during this phase of the authorisation process, as the assessment of wide dispersiveness during the prioritisation does not require detailed exposure assessment or an assessment on whether there is evidence (e.g. based on epidemiological data) that the substance is causing adverse effects, in this case respiratory sensitisation, in certain parts of the population. The assessment of wide dispersiveness of uses instead comprises a global evaluation of the substance’s use pattern, relying on some basic indicators – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of the prioritisation process. Furthermore, even if the assessment of control or exposure levels was considered beneficial during the prioritisation step, there is in this phase of the authorisation process no

objective information basis to do so, in particular, whether necessary measures are indeed implemented at sites and what exposure levels occur in different sites using the substance across the EU.

Regarding the types of actors involved, ECHA has acknowledged in the recommendation's background documents and responses to comments received that professional and consumer uses have been removed from the identified uses and now are advised against in almost all updated registrations. ECHA has reminded during the opinion forming that these updated registrations were already used as the basis for prioritisation. However, it needs to be stressed that according to the agreed prioritisation approach also industrial uses are considered wide dispersive as long as they occur at a sufficiently high number of sites and entail processes where significant exposure cannot be excluded. Also for all other substances in the Candidate List the industrial uses have been taken into account when assessing their priority for the inclusion in Annex XIV.

Finally, on the statements proposing alternative risk management options (such as binding occupational exposure limits), ECHA is of the view that discussion on the best regulatory options is not appropriate in the recommendation phase, and should be addressed in other fora.

In conclusion, ECHA would like to stress that, based on the criteria of Art. 58(3) of REACH and the information available to ECHA, ADCA gets high priority among the substances on the Candidate List assessed. Therefore ECHA recommends the substance for inclusion in Annex XIV.

Further details can be found in the substance specific background and RCOM documents.

2.2 Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name: Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)]
EC Number: 204-650-8
CAS Number: 123-77-3

2) Intrinsic properties of the substance

Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as a respiratory sensitiser, Resp. Sens. 1 (H334: "May cause allergy or asthma symptoms or breathing difficulties if inhaled"). Taking into account all available information on the intrinsic properties of diazene-1,2-dicarboxamide [C,C'-azodi(formamide), ADCA] and their adverse effects, it was concluded that the substance can be regarded as substance for which in accordance with Article 57 (f) of REACH there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Diazene-1,2-dicarboxamide [C,C'-azodi(formamide)] was identified as a Substance of Very High Concern (SVHC) according to Article 57 (f) and was therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on ADCA does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

During the public consultation comments on transitional arrangements were received. Apart from one comment appearing to request shortening the transitional arrangements, the comments mostly referred to extending the transitional arrangements based on arguments that more time is needed for developing and implementing alternatives (e.g. 5 to 8 years after inclusion) and/or for preparing applications for authorisation due to e.g. many SMEs involved in the supply chain and no experience in the process. ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards etc. is information which should be included in an eventual application for authorisation. Further details can be found in the '*Response to Comments Document for ADCA*'.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Latest application date:*
Date of inclusion in Annex XIV plus 21 months.
- *Sunset date:*
18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA did not receive comments requesting any concrete upfront review periods in accordance with article 58(1)(d) for uses of ADCA. Responses to general comments on review periods can be found in the '*Response to Comments Document for ADCA*'.

The information available was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. ECHA therefore does not recommend to include in Annex XIV any review periods for uses of ADCA.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of ADCA on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation ECHA received requests for use-specific exemptions of ADCA. Several such requests referred to uses of specific forms of the substance. Other requests referred to uses where e.g. risks were claimed to be controlled or where no suitable alternatives were claimed to exist.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013). Further details can be found in the '*Response to Comments Document for ADCA*'.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of ADCA on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) Application of authorisation to product and process oriented research and development (PPORD)

ECHA did not receive requests for exemption of ADCA from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of ADCA for PPORD from authorisation.

3. Aluminosilicate Refractory Ceramic Fibres (AI-RCF)

3.1 Reasons for prioritising Aluminosilicate Refractory Ceramic Fibres (AI-RCF)

AI-RCF is used in very high volumes in the scope of authorisation. The use of the substance is expected to take place at a high number of sites, and can potentially lead to significant worker exposure.^{14,15}

AI-RCF received high priority among the substances on the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Notes to MSC views

Concerns have been raised in the public consultation in relation to the clarity of the obligations to the duty holders would these substances be included in the authorisation list. These concerns are also reflected in the MSC opinion. ECHA stresses that substance identity aspects have been considered and decided in the context of inclusion of the substance in the Candidate List. Similar comments on the substance identity of RCFs have been addressed by the dossier submitter during the public consultation that took place when identifying the substance as SVHC¹⁶. In the prioritisation ECHA has only considered uses of the substances falling within the scope of the Candidate List entries. A further aspect claimed to potentially cause confusion is the fact that the two entries for RCFs in the Candidate List and included in this recommendation are based on one entry in Annex VI of the CLP Regulation. In this context, ECHA has, in its responses to comments and during the MSC discussions reminded, that such aspects have been addressed during the inclusion in the Candidate List and has provided an explanation as to how the substance identity description fulfils the REACH requirements.

ECHA has furthermore clarified that the CLP entry for RCFs refers to a group of substances and that the only additional information necessary for establishing whether a substance covered by the RCF entry in Annex VI of the CLP Regulation corresponds to one of the two RCFs in the candidate list is the identity of the main components in the fibres. That information is expected to be available in the supply chain, the identity of the main components being normally determined by the identity and ratio of the starting materials used for the manufacturing of the RCFs. Where needed, this information can also be derived from elemental analysis of the fibres.

¹⁴ The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

¹⁵ The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

¹⁶ See e.g. comments on Annex XV dossier for identification of AI-RCF as SVHC and responses to these comments by the dossier submitter (<http://echa.europa.eu/documents/10162/f00a3670-b2c0-4d20-9685-dae7e6c8f78>)

ECHA has provided further clarification on aspects related to the substance identity of RCFs in the substance specific RCOM documents (e.g. regarding the concentrations of other oxides that are sometimes incorporated to adjust the properties of the fibres) and is prepared to explore further means to make this guidance and advice more accessible to potential duty holders.

ECHA has also provided further clarification in its responses to comments and during the MSC discussions on whether certain products containing RCFs should be considered as substances/mixtures or articles. Duty holders are referred to the "Guidance on requirements for substances in articles", which provides support for differentiating substances/mixtures from articles. As for any other substance, it is often not possible for ECHA to conclude at which stage of the lifecycle (and for which specific products) the status of these RCFs may change from substances to articles. This is not either necessary during the recommendation step of the authorisation process. In this context, ECHA has during the MSC discussions and in its responses to comments also noted that potential applicants for authorisation of uses which result in incorporation of RCFs in articles need to cover in their applications the whole life cycle of RCFs including the service-life and waste stages of the articles.

Finally, on statements proposing alternative risk management options and/or considerations regarding the extent to which for current uses of RCFs suitable alternatives exist / risks are controlled / socioeconomic benefits outweigh the risks, ECHA notes that discussion of such aspects is not within the scope of the recommendation phase.

Further details can be found in the substance specific background and RCOM documents.

3.2 Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm) c) alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18% by weight.

Chemical name: Aluminosilicate Refractory Ceramic Fibres

EC Number: -

CAS Number: -

2) Intrinsic properties of the substance

Aluminosilicate Refractory Ceramic Fibres (Al-RCF) were identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) as they are classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as

carcinogen, Carc. 1B (H350i: "May cause cancer"), and were therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decisions ED/77/2011 and ED/95/2012.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD).

The information available on AI-RCF does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

During the public consultation comments on transitional arrangements were received. Apart from one comment appearing to request shortening the transitional arrangements, the comments mostly referred to extending the transitional arrangements based on arguments that more time is needed for developing and implementing alternatives (e.g. adaption/redesigning/re-validation of processes and products), for continuing use of products with long service life / production of spare parts, and/or for organising and preparing applications for authorisation (due to e.g. high number of products impacted, complexity of supply chain, the SME nature of sector, and no experience in the process). Requested time periods ranged from having a minimum LAD of 30 months to more than 30 years after inclusion. ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards etc. is information which should be included in an eventual application for authorisation. Further details can be found in the '*Response to Comments Document for AI-RCF*'.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Latest application date:*
Date of inclusion in Annex XIV plus 21 months
- *Sunset date:*
18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of AI-RCF. Those comments suggested review periods of e.g. 5 to 20

years for certain uses. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Response to Comments Document for Aluminosilicate Refractory Ceramic Fibres (AI-RCF)'*.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of AI-RCF.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of AI-RCF on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions but also a number of requests for exemptions of AI-RCF, either use-specific or requesting to exempt all uses of a certain industrial sector. Several requests referred to existing EU legislation, while there were also comments referring to the current discussion of a binding occupational exposure limit value (BOELV) and its potential implementation in the near future, as well as to other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2013). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of AI-RCF. It was however noted that if discussions under the Carcinogens and Mutagens Directive would lead to a binding OEL, a revisit of the respective exemption request may be warranted. Finally, it is also noted that some of the uses requested to be exempted may already qualify for exemption under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the *'Response to Comments Document for AI-RCF'*.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of AI-RCF on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) Application of authorisation to product and process oriented research and development (PPORD)

ECHA did not receive requests for exemption of AI-RCF from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of AI-RCF for PPORD from authorisation.

4. Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)

4.1 Reasons for prioritising Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)

Zr-RCF is used in high volumes in the scope of authorisation. The use of the substance is expected to take place at a high number of sites, and can potentially lead to significant worker exposure.^{17,18}

Zr-RCF received high priority among the substances on the Candidate List assessed; hence ECHA has recommended it for inclusion in Annex XIV.

Notes to MSC views

See notes at section 3.1 (on Al-RCF) of this Annex.

4.2 Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of 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, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm). c) alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18% by weight.

Chemical name:	Zirconia Aluminosilicate Refractory Ceramic Fibres
EC Number:	-
CAS Number:	-

2) Intrinsic properties of the substance

Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) were identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) as they are classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as

¹⁷ The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

¹⁸ The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents. <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

carcinogen, Carc. 1B (H350i: "May cause cancer"), and were therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decisions ED/77/2011 and ED/95/2012.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD).

The information available on Zr-RCF does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

During the public consultation comments on transitional arrangements were received. Apart from one comment appearing to request shortening the transitional arrangements, the comments mostly referred to extending the transitional arrangements based on arguments that more time is needed for developing and implementing alternatives (e.g. adaption/redesigning/re-validation of processes and products), for continuing use of products with long service life / production of spare parts, and/or for organising and preparing applications for authorisation (due to e.g. high number of products impacted, complexity of supply chain, the SME nature of sector, and no experience in process). Requested time periods ranged from having a minimum LAD of 30 months to more than 30 years after inclusion. ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards etc. is information which should be included in an eventual application for authorisation. Further details can be found in the '*Response to Comments Document for Zr-RCF*'.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Latest application date:*
Date of inclusion in Annex XIV plus 21 months
- *Sunset date:*
18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for several uses of Zr-RCF. Those comments suggested review periods of e.g. 5 to

more than 20 years for certain uses. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the '*Response to Comments Document for Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)*'.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Zr-RCF.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of Zr-RCF on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions but also a number of requests for exemptions of Zr-RCF, either use-specific or requesting to exempt all uses of a certain industrial sector. Several requests referred to existing EU legislation, while there were also comments referring to the current discussion of a binding occupational exposure limit value (BOELV) and its potential implementation in the near future, as well as to other justifications such as the control measures in place or the lack of suitable alternative substances.

ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of Zr-RCF. It was however noted, during the MSC discussions and in ECHA's responses to comments, that if discussions under the Carcinogens and Mutagens Directive would lead to a binding OEL, a revisit of the respective exemption request may be warranted. Finally, it is also noted that some of the uses requested exemptions may already qualify as exempt under the generic exemptions from authorisation as provided by the REACH Regulation. Further details can be found in the '*Response to Comments Document for Zr-RCF*'.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of Zr-RCF on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) Application of authorisation to product and process oriented research and development (PPORD)

ECHA did not receive requests for exemption of Zr-RCF from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation.

ECHA does not recommend exempting the use of Zr-RCF for PPORD from authorisation.

5. 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

5.1 Reasons for prioritising 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

These substances are used in high tonnage in products that can be assumed to lead to wide-dispersive emissions to the environment.^{19,20}

4-tert-OPnEO received high priority among the substances on the Candidate List assessed; hence ECHA has recommended them for inclusion in Annex XIV.

Notes to MSC views

Concerns have been raised in the public consultation in relation to the clarity of substance identity and consequently the obligations to the duty holders, would these substances be included in the authorisation list. These concerns are also reflected in the MSC opinion. ECHA stresses that substance identity aspects have been considered and decided in the context of inclusion of the substance in the Candidate List. Similar comments on the substance identity of 4-tert-OPnEO have been addressed by the dossier submitter during the public consultation that took place when identifying the substance as SVHC²¹.

ECHA has provided further clarification on aspects related to the substance identity of 4-tert-OPnEO in the substance specific RCOM documents and is prepared to explore further means to make such advice more accessible to potential duty holders.

5.2 Reasons for the specific items in the Annex XIV entry

1) Identity of the substance

Chemical name: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO)

EC Number: -

CAS Number: -

¹⁹ The qualifiers used for volumes, number of sites and exposure potential are further explained and described in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf)

²⁰ The prioritisation is based on registration data and other information made available during the SVHC identification and Annex XIV recommendation processes as described in the substance specific background and RCOM documents.
<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/5th-recommendation>

²¹ See e.g. comments on Annex XV dossier for identification of 4-tert-OPnEO as SVHC and responses to these comments by the dossier submitter (<http://echa.europa.eu/documents/10162/dc939f9a-707d-4187-90a2-57cc5b062d87>)

2) Intrinsic properties of the substance

The substances covered by the entry '4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]' were identified as substances meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because (through their degradation) they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. They were therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

3) Transitional arrangements

Article 58(1)(c)(ii) specifies that the latest application date (LAD) must be at least 18 months before the sunset date (SSD). The information available on 4-tert-OPnEO does not provide grounds for distinguishing sunset dates for different uses or to extend the 18 months time period between LAD and SSD set out in the legal text.

ECHA has determined the application dates as described in Recital (9) of the Recommendation.

During the public consultation comments on transitional arrangements were received. Apart from one comment appearing to request shortening the transitional arrangements, the comments mostly referred to extending the transitional arrangements based on arguments that more time is needed for developing and implementing alternatives (e.g. adaption/redesigning/re-validation of processes and products) for continuing the global supply. Time periods requested were such as more than 10 years, making reference also to the diversity of uses, the involvement of SMEs in the supply chain, and cases where more than one substance recommended for inclusion in Annex XIV is used in the production of the same (In Vitro Diagnostic) products. ECHA has assessed all these requests on the basis of the approach set out in the document '*Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach*' (2013) and has not found grounds to deviate from the originally determined transitional arrangements. ECHA also reminds that there is no need to have the transfer to alternatives finalised before the sunset date and that information such as the present lack of alternatives to (some of) the uses of a substance or information about established safety requirements or performance standards etc. is information which should be included in an eventual application for authorisation. Further details can be found in the '*Response to Comments Document for 4-tert-OPnEO*'.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

- *Latest application date:*
Date of inclusion in Annex XIV plus 24 months.
- *Sunset date:*
18 months after the application date.

4) Review periods for certain uses

During the public consultation on the draft Recommendation, ECHA received comments on setting review periods in accordance with article 58(1)(d) for uses in In Vitro Diagnostics, of 10 years. The information available, including the information provided in the comments, was assessed as not sufficient to support determination of review periods in accordance with article 58(1)(d) for any use of the substance. Further details can be found in the *'Response to Comments Document for 4-tert-OPnEO'* (2014).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of 4-tert-OPnEO.

5) Exempted (categories of) uses

In its draft Recommendation for public consultation, ECHA had not proposed any exemptions for (categories of) uses of 4-tert-OPnEO on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation on the draft Recommendation, ECHA received support for not proposing any exemptions but also a number of requests for exemptions of 4-tert-OPnEO. Some requests referred to existing EU legislation, while there were also requests based on other justifications such as the risk management measures in place or the lack of suitable alternative substances. There were also comments requesting exemption for formulation / packaging / refilling uses taking place in the supply chain prior to certain uses (e.g. uses for SRD, production of medicinal products, In Vitro Diagnostics, cleaning of medicinal equipment etc.).

ECHA has assessed all these requests on the basis of the approach set out in the document *'Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General approach'* (2013). ECHA concluded that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses of 4-tert-OPnEO. Finally, it was also noted, in ECHA's responses to comments, that some of the uses requested exemptions may already qualify as exempt under generic exemptions from authorisation. Further details can be found in the *'Response to Comments Document for 4-tert-OPnEO'*.

In conclusion, ECHA could not identify grounds to recommend exemptions of uses of 4-tert-OPnEO on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

6) Application of authorisation to product and process oriented research and development (PPORD)

ECHA received and assessed requests for exemption of 4-tert-OPnEO from the authorisation requirement for product and process oriented research and development on the basis of Article 56(3) of the REACH Regulation. These requests mainly referred to PPORD activities for the production of medical

diagnostic products or in general biochemical applications and asked for e.g. volumes up to 10 t/y to be exempted.

ECHA considers that in accordance with Article 55 of REACH one of the aims of Authorisation is progressive replacement of SVHCs where this is technically and economically viable. Therefore, any further PPORD activities which may require the use of a substance included in Annex XIV should in principle aim at developing alternative substances and technologies to replace the SVHC in question or to further develop processes to improve the control of risks until feasible alternatives are available. However, ECHA notes that actors can apply for a use of a substance (included in Annex XIV) for any PPORD activity and the pertinence of a PPORD activity with a substance identified as SVHC should be justified in an authorisation application and be scrutinized and decided in the authorisation granting process in accordance with Article 60.

In conclusion, ECHA could not find grounds to recommend exempting the use of 4-tert-OPnEO for PPORD from authorisation.