10 February 2021 Final

OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT TENTH RECOMMENDATION OF THE PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION AND THE ASSOCIATED ANNEX XIV ENTRIES

Adopted on 10 February 2021

OPINION

This opinion of the Member State Committee (MSC) is on the draft 10th recommendation of European Chemicals Agency (ECHA) concerning priority substances to be included in Annex XIV. The opinion was adopted on 10 February 2021 in accordance with Article 58(3) of the REACH Regulation (EC) No 1907/2006[1].

THE DRAFT TENTH RECOMMENDATION OF ECHA

The draft 10th recommendation for priority substances to be included in Annex XIV of REACH (hereafter referred to as the "draft 10th recommendation") prepared by ECHA included seven substances and specified the following information for priority substances:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property(-ies) of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date
    - The application date

No review periods, uses or categories of uses exempted from the authorisation requirement or PPORD exemptions were specified in the draft 10th recommendation.

The draft 10th recommendation addressed in the consultation is attached to this opinion (Annex II).

FOCUS OF THE OPINION OF MSC

The opinion of MSC focuses on the draft 10th recommendation and the comments received during the consultation. Further details of the information taken into account by MSC in the preparation of its opinion and further justification for MSC views are presented in the support document (see Annex I).

[1] Regulation (EC) No 1907/2006 of the European Parliament and 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

Emphasis in the support document is given to comments received and issues raised during the consultation that are not specifically addressed in *'ECHA's general responses on issues commonly raised in consultations on draft recommendations'* [2] document.

OPINION OF MSC ON THE TENTH DRAFT RECOMMENDATION FOR PRIORITISATION OF SUBSTANCES TO BE INCLUDED IN ANNEX XIV

PRIORITISED SUBSTANCES

MSC is of the opinion that no information has been received that would justify not including all 7 substances in the final recommendation. MSC is of the opinion that all substances listed in ECHA´s draft 10th recommendation and as indicated in the table below, fulfil the prioritisation criteria and should be prioritised for inclusion into Annex XIV in accordance with Article 58(3) of REACH.

#	Substance	EC number	CAS number
1	Octamethylcyclotetrasiloxane (D4)	209-136-7	556-67-2
2	Decamethylcyclopentasiloxane (D5)	208-764-9	541-02-6
3	Dodecamethylcyclohexasiloxane (D6)	208-762-8	540-97-6
4	Terphenyl, hydrogenated	262-967-7	61788-32-7
5	Dicyclohexyl phthalate (DCHP)	201-545-9	84-61-7
6	Disodium octaborate	234-541-0	12008-41-2
7	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7

TRANSITIONAL ARRANGEMENTS

MSC notes that the draft 10th recommendation of ECHA proposed to allocate the substances to one of three latest application date (LAD) slots, 18, 21 or 24 months after the date of inclusion in Annex XIV. ECHA indicated that the final LAD allocation for each substance/substance group would be done taking into account all available information including feedback from the consultation and registration updates. Sunset dates for all substances were proposed as LAD plus 18 months.

Following the consultation, ECHA proposed LADs for each substance/substance group which are presented in the table below.

Taking into account all available information, the MSC is of the opinion that the LAD allocation proposed by ECHA is appropriate.

Substance / Group	No. of substances in Group	Proposed LAD
Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	1	18 months
Dicyclohexyl phthalate (DCHP)	1	18 months
Terphenyl, hydrogenated	1	21 months
Siloxanes[3]	3	24 months

[2] https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c (version 5 March 2020)

Substance / Group	No. of substances in Group	Proposed LAD
Disodium octaborate	1	24 months

MSC is also of the opinion that the sunset date for all substances should be assigned as the LAD plus 18 months.

REVIEW PERIODS FOR CERTAIN USES

In its draft 10th recommendation, ECHA did not recommend any review period.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV.

USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

In its draft 10th recommendation, ECHA did not recommend any uses or categories of uses that should be exempted from authorisation pursuant to Article 58(2) of REACH.

MSC is of the opinion that there is currently not a clearly sufficient basis for recommending exemptions in Annex XIV for the prioritised substances under Article 58(2) of REACH.

MSC notes the upcoming restriction[4] on siloxane substances that covers the placing on the market of D4, D5 and D6 in consumer and professional products. MSC further notes that ECHA refers to the European Commission who decides on the upcoming restriction of D4, D5 and D6, on the Annex XIV inclusion and considers whether conditions for an exemption under Article 58(2) of REACH could be met once this restriction is adopted. MSC is of the opinion that the restriction cannot be taken into account at this stage. However, MSC would like ECHA to invite the European Commission to review the possibility for an exemption under Article 58(2) at the stage of drafting of, and discussions amongst REACH Committee experts on, the Annex XIV entry for the siloxane substances D4, D5 and D6, as the final scope of the restriction will be known at that stage.

EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

ECHA in its draft 10th recommendation did not recommend any exemptions from the authorisation requirements for uses in product and process oriented research and development (PPORD), as provided for in Article 56(3) of REACH. No requests for exemptions for PPORD were received during the consultation.

MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

OTHER ISSUES

MSC is of the opinion that no additional issues were raised in the consultation which would lead to a different opinion on the draft 10th recommendation.

---

[3] Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), dodecamethylcyclohexasiloxane (D6)
[4] https://echa.europa.eu/sk/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade

Annex I: Support document for the opinion of MSC
Annex II: ECHA's draft 10th recommendation for Annex XIV, published on 5 March 2020

ECHA
EUROPEAN CHEMICALS AGENCY

ANNEX TO THE MEMBER STATE COMMITTEE'S OPINION ON ECHA'S DRAFT TENTH RECOMMENDATION (ADOPTED ON 10 FEBRUARY 2021)

ANNEX I SUPPORT DOCUMENT FOR THE OPINION OF MSC

ANNEX II DRAFT RECOMMENDATION OF PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION AS SUBMITTED FOR CONSULTATION ON 5 MARCH 2020

ANNEX I

SUPPORT DOCUMENT FOR THE OPINION OF THE MEMBER STATE COMMITTEE ON ECHA'S DRAFT TENTH RECOMMENDATION OF PRIORITY SUBSTANCES TO BE INCLUDED IN ANNEX XIV OF THE REACH REGULATION (ADOPTED ON 10 FEBRUARY 2021)

1. INTRODUCTION

In accordance with Article 58(3) of REACH, the Member State Committee (MSC) must provide an opinion on ECHA's draft recommendation for priority substances to be included in Annex XIV of REACH (hereafter referred to as the "draft recommendation"). ECHA takes into account the opinion of the MSC, as well as comments received during the consultation, when finalising its recommendation for priority substances to be included in Annex XIV of REACH to be sent to the European Commission for decision making.

This support document aims at providing background information on the process for adoption of the MSC opinion on the draft recommendation, the information taken into account by MSC in forming its opinion and further details on the grounds for MSC's views on the draft 10th recommendation.

The aim of this document is not to reproduce the full information justifying the prioritisation of the substances or to summarise all the comments received during the consultation. Rather, emphasis is given to comments received and issues raised that are not addressed in '*ECHA's general responses on issues commonly raised in consultations on draft recommendations*'[5] document.

2. PROCESS FOR ADOPTION OF THE OPINION

ECHA published its draft 10th recommendation on 5 March 2020 on its website for consultation. The draft 10th recommendation addressed in the consultation is included in Annex II of the MSC Opinion.

MSC was requested to provide an opinion to ECHA on the draft 10th recommendation. The opinion of MSC considers whether the substances that ECHA has prioritised meet the criteria of Article 58(3) of REACH for prioritisation of substances from the candidate list for inclusion in Annex XIV, using the agreed approach presented in the document on prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)[6] and the document on general approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[7].

MSC appointed a Rapporteur and a Co-Rapporteur for preparing its opinion on ECHA's draft 10th recommendation and a Working Group to support the Rapporteur and the Co-Rapporteur at its 71st meeting (13-14 October 2020).

For the preparation of its opinion the MSC took into account:

- ECHA's priority setting approach and its application to all substances on the candidate list not already included or recommended for inclusion in Annex XIV of REACH
- General approach for defining the REACH Annex XIV entries[7]

[5] https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c (version 5 March 2020)
[6] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[7] http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

- ECHA's draft 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (available for consultation on ECHA website on 5 March 2020)[8]
- (Draft) Background documents for each substance summarising the available information used for priority setting at the start of the consultation and specification of draft REACH Annex XIV entries prepared by ECHA (published 5 March 2020 on the ECHA website in the context of the consultation)
- Comments of the interested parties provided during the consultation period that started on 5 March 2020 and closed on 5 June 2020. In its review of the comments received, MSC also took into account 'ECHA's general responses on issues commonly raised in consultations on draft recommendations'
- Preliminary assessment by the ECHA Secretariat of the information received during the consultation and its potential impact on the Annex XIV entries, including
    - Updated prioritisation table (with a summary of changes)
    - Table with proposed latest applications dates (slots) after closure of the consultation
- Draft responses to comments as provided by the ECHA Secretariat to the Rapporteur and Working Group as supportive material during the process (by 30 October 2020 and in updated versions of 26 November 2020 and 28 January 2021).

The Rapporteur and the Co-Rapporteur, supported by the Working Group, assessed the above information, together with input from MSC, for drafting the opinion of MSC on the draft 10th recommendation.

The draft opinion provided to the MSC by the Rapporteur was finalised and adopted on 10 February 2021 after discussion at the **73rd** meeting of MSC.

3. MSC VIEWS ON THE RECOMMENDATION

3.1 PRIORITISED SUBSTANCES LISTED IN THE DRAFT 10TH RECOMMENDATION

In its draft 10th recommendation, ECHA proposed seven substances for possible inclusion in Annex XIV. The substances are listed in the following table:

#	Substance	EC number	CAS number
1	Octamethylcyclotetrasiloxane (D4)	209-136-7	556-67-2
2	Decamethylcyclopentasiloxane (D5)	208-764-9	541-02-6
3	Dodecamethylcyclohexasiloxane (D6)	208-762-8	540-97-6
4	Terphenyl, hydrogenated	262-967-7	61788-32-7
5	Dicyclohexyl phthalate (DCHP)	201-545-9	84-61-7
6	Disodium octaborate	234-541-0	12008-41-2
7	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7

[8] https://echa.europa.eu/documents/10162/13640/10th_recom_draft_axiv_entries_en.pdf/654ecb99-432f-1f15-ee66-def3ed16c362

MSC is of the opinion that no information was received during the consultation that would justify not including all seven substances, as indicated in the table above, in the final recommendation. MSC is of the opinion that prioritisation is justified for all substances/substance groups due to the intrinsic properties, the volume used in the scope of authorisation and the wide dispersiveness of use or based on grouping considerations.

3.1.1 COMMENTS RECEIVED ON PRIORITISATION DURING CONSULTATION

During the consultation, comments were received on most substances that challenged the prioritisation of the substances. MSC considered all the comments in preparing its opinion. MSC notes that many of the comments were similar across several substances and these are addressed in section 3.1.1.1 below. In addition to the comments that were similar across several substances, some comments were received which related to individual substances only. These were noted by MSC and are addressed in section 3.1.1.2 below, where deemed relevant.

3.1.1.1 COMMON ELEMENTS FOR ALL SUBSTANCES / SUBSTANCE GROUPS

As indicated above, comments were received from industry that were similar across several substances. These addressed such issues as authorisation not being the most appropriate risk management measure to control risk, that other regulatory processes would be more appropriate and that there are already measures in place to control risks and so there is no need to prioritise the substances. For some substances, the comments indicated that a (targeted) restriction would be more appropriate and/or referred to existing RMOA. For others, it was indicated that there are other regulatory measures that already exist for the substance and that these should be taken into account when considering prioritisation. Some comments also made the point that any risks could be controlled by means of appropriate safety and risk management measures already in place.

On the above aspects, MSC notes ECHA's view expressed in its '*responses to issues commonly raised in consultations on draft recommendations*' document and is of the opinion that such requests not to prioritise the substances for authorisation are not justified.

3.1.1.2 SUBSTANCE SPECIFIC ISSUES ON PRIORITISATION

Siloxanes

The term "siloxanes" covers the three substances octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6).

During the consultation comments were received from industry that challenged the prioritisation of the three siloxane substances into Annex XIV. Reference was made to an upcoming restriction under REACH Annex XVII, for which in January 2019 a proposal was made by ECHA at the request of the Commission, and which aims at restricting D4, D5 and D6 in consumer and professional products[9]. In many comments restriction was seen as the most appropriate EU-wide measure to regulate the use and placing on the market of D4, D5 and D6. Furthermore, it is claimed by

[9] The final RAC/SEAC opinion was adopted on 12 March 2020 and is available on ECHA website https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade

commentators that derogations, as included in the draft scope of the restriction and mostly relating to industrial uses, should lead to exemptions from authorisation as well.

MSC has considered these arguments and agrees with ECHA that authorisation and restriction can be used in a complementary manner to ensure proper control of risk and provide an incentive to (continue to) substitute the SVHCs, i.e. they do not exclude each other. MSC notes that RAC and SEAC considered in their joint opinion the upcoming restriction as the most appropriate EU wide measure to address the risks posed by the use of D4, D5 and D6 in consumer and professional products. However, the committees only assessed those uses that were covered by the restriction proposal. Furthermore, uses of D4, D5 and D6 foreseen to be derogated from the upcoming restriction in general fall within the scope of authorisation (see also section 3.4). MSC agrees with ECHA that the decisions on the interplay of the upcoming restriction of D4, D5 and D6 on the Annex XIV inclusion and on possible exemptions pursuant to Article 58(2) of REACH are taken by the Commission. This enables the Commission to make sure that the regulatory decisions are taken in a complementary manner.

Some comments were challenging the inherent properties (PBT, vPvB) of D4, D5 and D6. MSC considers that this is not relevant at this stage of the process as the substances have been identified as SVHCs and included on the candidate list.

Several comments were also received which were relevant for the scoring of the siloxanes and some of the registrations have been updated. Furthermore, ECHA has taken into account the scope of the upcoming restriction.

In many comments, claims have been made that manufacture of silicone polymers is an intermediate use which is generally exempt from authorisation. MSC notes that for the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of D4, D5 and/or D6 as monomers in the manufacture of silicone polymers and other polymers. Based on the current state of play of the interpretation of the intermediate status following the European Court of Justice's judgment in Case C-650/15 P, ECHA has not taken a position whether this use qualifies as intermediate use. MSC is of a similar opinion to ECHA in this regard and supports the approach taken by ECHA.

Other comments claimed that the presence of unreacted monomers of D4, D5 and D6 in silicone polymer is exempt from authorisation even if D4, D5 and/or D6 are present above the concentration limits laid down in REACH Article 56(6). MSC notes the ECHA Q&A (Nr. 565), which addresses this issue. According to that Q&A, if D4, D5 and/or D6 are present in a polymer as unreacted monomers, they would not be subject to authorisation (unless specified in the Annex XIV entry). MSC further notes that if D4, D5 and/or D6 are added intentionally to a polymer/substance above a concentration limit of 0.1%, this would constitute a mixture and the use of the mixture would require authorisation. MSC notes that ECHA did not take the use of the substances in the manufacture and use of silicone polymers and the related volumes (including unreacted monomers) into account for prioritisation purposes and MSC can support this approach.

Comments have also been received specifically on the individual siloxanes.

For D4 several comments challenged the volumes and wide-dispersiveness of certain uses. Industry claimed that certain uses of D4 are exempted from authorisation especially related to intermediate uses. The volume of D4 within the scope of authorisation was also challenged. ECHA has, when assessing their intermediate status for some of these uses applied a reasonable worst case approach and assumed the uses and related volumes that are relevant for prioritisation. The MSC is in agreement with the approach taken by ECHA. Additionally, for D4 ECHA did not expect

any impact on volume and WDU if the upcoming restriction will be adopted with its current scope. Taking into account the information from updated registrations and information from the consultation on volumes for D4, a slight adjustment of volume within the scope of authorisation lead to a decrease from 12 to 9-12, with a total middle score of now 33 instead of 34. MSC agrees with the approach taken by ECHA.

For D5 MSC notes that ECHA has lowered the volume score from 12 to 9-12, taking into account uncertainties on remaining uses in the scope of authorisation after adjustment to the foreseen scope of the upcoming restriction. Accounting for professional uses derogated from the upcoming restriction and update for article service-life resulted in a higher WDU score of 11 instead of 7 and hence a total score (middle value) of 37 instead of 34. MSC agrees with the approach taken by ECHA.

For D6 most uses currently falling within the scope of authorisation would be within the scope of the upcoming restriction. Taking into account uncertainties in the remaining volumes, the score has been adjusted from 9 to 6-9. Remaining uses would be the formulation for export and minor professional use derogated from the restriction, which led to an increase in WDU score from 5 to 7 and to an increase in total score (middle value) from 29 to 30. MSC agrees with the approach taken by ECHA.

MSC notes that, even if there are some doubts regarding the interpretation of intermediate uses, the changes in scores for D4, D5 and D6 do not affect the overall prioritisation of these substances as the total prioritisation scores remain high and MSC agrees that all three siloxane substances should be prioritised for inclusion in Annex XIV, which is further strengthened by grouping considerations.

Terphenyl, hydrogenated

MSC notes that most of the comments received during the consultation from industry were related to the uses of terphenyl, hydrogenated, as heat transfer fluid in closed, tight systems at industrial sites operated under controlled conditions.

Industry challenged prioritisation of terphenyl, hydrogenated, claiming that vPvB substances do not fulfil the T-criteria and are considered of concern due to the precautionary assumption that increasing concentrations may cause adverse effects after prolonged exposure. Applying the precautionary principle rather than taking due consideration of environmental relevance might not be the right approach for prioritisation. MSC considers that this is not relevant for this stage of the process as the substance has been identified as an SVHC and included on the candidate list.

There were many comments received from industry expressing the view that a targeted restriction would be a more adequate regulatory measure, in order to ban uses of terphenyl, hydrogenated leading to an unacceptable risk, and allow for uses as heat transfer fluid in closed systems under defined safe and controlled conditions without any exposure and environmental releases. In industry´s view, authorisation of heat transfer fluids in closed systems will not further reduce existing risk. MSC is of the opinion that it is not appropriate to assess if other risk management measures would be more appropriate at this stage of the process. Moreover, MSC also notes comments stating that some heat transfer fluid closed systems require partial annual replenishment of terphenyl, hydrogenated. Refill procedure involves transportation to the site of use, opening of closed system, collection of used fluid, loading, transport and elimination of used fluid. In this regard, exposure of humans and the environment related to the uses of terphenyl, hydrogenated as heat transfer fluid in closed systems cannot be excluded.

Comments were also received from industry requesting to regulate all substances used as heat transfer fluids simultaneously or to postpone the recommendation of terphenyl, hydrogenated, until regulatory future of alternative substances is clarified. In those comments it was indicated that all high temperature non-pressurized heat transfer fluids must possess properties that likely qualify them to meet REACH Annex XIII criteria for persistence and bioaccumulation. The functional grouping of similar substances should be taken into account as a part of prioritisation assessment in order to avoid regrettable substitution in the future.

MSC notes that two potential substitution candidates[10] to terphenyl, hydrogenated, used as heat transfer fluid have been positively screened for PBT or vPvB. There are evaluation processes currently ongoing for both substances in order to clarify their environmental hazard. MSC is of the opinion that based on current state of knowledge, regulation of terphenyl, hydrogenated, in parallel with potential alternative substances is not feasible and therefore, MSC is in agreement with the approach taken by ECHA.

Dicyclohexyl phthalate (DCHP)

Industry challenged the volume of dicyclohexyl phthalate in the scope of authorisation. MSC notes that, based on the updated information in the registration dossiers, ECHA lowered the assigned volume score from 12 to 9. This adjustment resulted in a decrease of total prioritisation score from 31 to 28. MSC agrees with the approach taken by ECHA.

A further comment argued that no consumer uses or inclusion in articles are identified for DCHP and challenged the assigned refined WDU score. The comment submitter also argued that the restricted use of DCHP in articles would reduce the exposure. In this regard, ECHA clarifies that DCHP is so far only restricted for use in specific types of articles under entry 3 of Annex XVII of REACH. ECHA also points out that while some registrants do not longer report the incorporation of the substance into articles, the use of the substance in the articles is still reported in other registration dossiers or in the substances in articles notifications. ECHA further points out that consumer uses reported in the registration dossiers are considered to be covered by the restriction in Annex XVII (entry 30) and consequently, they were not taken into account for the prioritisation assessment. Based on above considerations, MSC notes that ECHA has not adjusted WDU score as requested by industry and the initial assigned WDU refined score of 12 is kept. MSC agrees with the approach taken by ECHA.

MSC also notes comments received from industry challenging the grouping approach based on a possible substitution of other phthalates already included in the Authorisation List. As stated by ECHA, although it is acknowledged that uses indicated as the basis for the grouping are no longer reported in some registration dossiers, the interchangeability is feasible based on reasonable worst case assumptions. MSC is of the opinion that the grouping approach is justified.

MSC agrees with the revised total prioritisation score of 28 for dicyclohexyl phthalate and notes that it does not affect the overall prioritisation of the substance as prioritisation is further strengthened by grouping considerations.

Disodium octaborate

During the consultation, a comment was received from industry and trade association stating that although the scoring and the prioritisation of disodium octaborate is in accordance with REACH and

[10] Dibenzylbenzene, ar-methyl derivative (EC 258-649-2) and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (EC 400-370-7)

the ECHA guidance on prioritisation, they questioned the prioritisation of a substance where substitution is not possible for more than 90% of its uses. They emphasised that the substance is used as a fertiliser, as boron is an essential micronutrient for plants and substitution is not considered possible. MSC notes ECHA´s response referring to the CARACAL paper "Criteria for longer review periods" (CA/101/2017) where this situation is addressed. As stated by ECHA, in case the main function of a substance is to provide a source of biological essential inorganic micronutrient for plants, longer review periods might be set in the application for authorisation phase.

MSC notes that grouping considerations have been taken into account for the prioritisation of the substance, as it is assumed that disodium octaborate can potentially replace other borate compounds already included in the 6th Annex XIV recommendation. The decision on the inclusion in Annex XIV of those borate compounds from the 6th recommendation was postponed temporarily due to the limited experience for handling authorisation applications covering broad ranges of uses. MSC is of the opinion that prioritisation of disodium octaborate with an assigned total prioritisation score of 25 further strengthened by grouping considerations is appropriate.

Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride; TMA)

Benzene-1,2,4-tricarboxylic acid 1,2 anhydride has been identified as a substance that could potentially substitute HHPA[11] and MHHPA[12], which were included in the 9th Annex XIV recommendation.

Industry challenged the grouping approach, claiming that TMA is not considered a suitable alternative and common uses as epoxy resin hardeners are not reported in the registration dossiers. Another comment pointed to structural and physicochemical differences between TMA and (M)HHPA. On the contrary, one Member State commented in favour of grouping based on structural similarities and the potential of the substance to be used in the same type of applications as MHHPA and HHPA. MSC notes that the information received during the consultation does not allow a conclusion that intersubstitutability of these substances for some of their uses is not feasible. MSC is of the opinion that the grouping approach is justified.

A comment was also received from industry claiming that the tonnage band as reported in the background document is highly inaccurate and does not represent the precise market size. MSC notes that the exact volume of the substance as claimed by industry is within the range reported in the background document. MSC deems this issue not relevant for the prioritisation as all uses of TMA are considered outside the scope of authorisation and volume score of zero is assigned to the substance in the prioritisation assessment.

3.2. TRANSITIONAL ARRANGEMENTS: LATEST APPLICATION DATE AND SUNSET DATE

In its draft 10th recommendation, ECHA proposed to set the latest application date (LAD) to one of three slots: 18, 21 or 24 months after the date of inclusion in Annex XIV. ECHA indicated the final allocation of the substances into those slots would be made after the consultation, taking all new

[11]Cyclohexane-1,2-dicarboxylic anhydride [1] (EC 201-604-9), cis-cyclohexane-1,2-dicarboxylic anhydride [2] (EC 236-086-3) and trans-cyclohexane-1,2-dicarboxylic anhydride [3] (EC 238-009-9). The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1]

[12]Hexahydromethylphthalic anhydride [1] (EC 247-094-1), hexahydro-4-methylphthalic anhydride [2] (EC 243-072-0), hexahydro-1-methylphthalic anhydride [3] (EC 256-356-4) and hexahydro-3-methylphthalic anhydride [4] (EC 260-566-1). The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1]

information available into account. Sunset date for all substances was proposed as the LAD plus 18 months.

MSC notes ECHA's general principles to setting LADs:

- Substances with no registration requirement or those which are not registered should be assigned a longer LAD
- Substances with complex supply chains and high number of uses should be assigned a longer LAD
- Substances considered as a group should preferably be included together in same LAD slot
- Assignment of substances to slots should support balanced workload for the ECHA Committees/ European Commission

Following the consultation, ECHA analysed information available on the complexity of the supply chain for each prioritised substance/substance group and used that information to derive a 'complexity of supply chain score'. Using that score, ECHA then proposed LADs for each substance/substance group which are presented in the table below. Substances/substance groups with the lowest scores were assigned to the 18 month slot, while substances/substance groups with the highest scores were assigned to the 24 month slot.

During the consultation, comments in relation to transitional arrangements were received on most of substances.

Comments received for siloxane substances referred to the big variety of uses of D4, D5 and D6 and the complexity of supply chains and LADs of 24 months are therefore requested. Furthermore, comments were received asking for alignment of transitional arrangements with the restriction transitional period. MSC agrees with ECHA that the decisions on the interplay of the upcoming restriction of D4, D5 and D6, on the Annex XIV inclusion and on possible exemptions pursuant to Article 58(2) are taken by the Commission.

Comments received for terphenyl, hydrogenated, requested to consider typical authorisation timeframes for use of the substance as heat transfer fluid in order to reflect typically longer life/investment cycles of plants using these technologies. MSC notes ECHA´s response that the length of the applicant's investment cycle is one criterion considered when setting review periods at the application phase of the authorisation process and thus is not relevant for assigning the LAD.

Comments received for dicyclohexyl phthalate requested LAD of 24 months instead of the proposed 18 months to await for the outcome of environmental endocrine disruption assessment of the substance. It is noted that there is an OECD TG 234 in progress under substance evaluation. MSC agrees with ECHA that this cannot be used as an argument at this stage of the process.

MSC reviewed these comments and is of the opinion that no information was provided that would result in a different LAD than that proposed by ECHA following their analysis post the consultation. Therefore, MSC is of the opinion that LADs presented in the table below are appropriate.

Substance / Group	No. of substances in Group	Proposed LAD
Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	1	18 months
Dicyclohexyl phthalate (DCHP)	1	18 months
Terphenyl, hydrogenated	1	21 months

Substance / Group	No. of substances in Group	Proposed LAD
Siloxanes[13]	3	24 months
Disodium octaborate	1	24 months

MSC is of the opinion that the sunset date for all substances should be set as the LAD plus 18 months.

3.3. REVIEW PERIODS FOR CERTAIN USES

No review period was suggested by ECHA in its draft 10th recommendation.

MSC notes comments received from industry on decamethylcyclopentasiloxane (D5) requesting a review period of at least 5 years for use in the pharmaceutical industry and on terphenyl, hydrogenated, requesting to consider typical authorisation review period timeframes for use of the substance as heat transfer fluid in order to reflect typically longer life/investment cycles of plants using these technologies.

As the review period is closely connected to the use(s) for which the authorisation is requested and is set on a case-by-case basis when granting the authorisation, MSC is of the opinion that upfront specified review periods are not warranted in the recommendation.

3.4 USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

ECHA did not propose any specific exemption of uses or categories of uses in its draft 10th recommendation.

Requests for exemption of uses or categories of uses were received on the siloxane substances, terphenyl, hydrogenated and dicyclohexyl phthalate. The requests were motivated by the fact that some of the uses of the substances appear to fall under the generic exemptions from the authorisation requirement, by the existence of specific EU legislation addressing some of the uses (requests under Article 58(2) of REACH) or by other elements (requests that were not substantiated by reference to specific EU legislation). These requests, and MSC's consideration on them, are detailed below.

3.4.1 EXEMPTION REQUESTS FOR USES THAT APPEAR TO FALL UNDER THE GENERIC EXEMPTIONS FROM THE AUTHORISATION REQUIREMENT

There were exemption requests for siloxane substances and terphenyl, hydrogenated regarding uses that appear to fall under the generic exemptions from authorisation, such as use as an intermediate (Article 2(8)(b) of REACH) or use in research and development (Articles 3(23) and 56(3) of REACH). MSC is of the view that industry has to examine whether the specific uses of a substance can be regarded as uses where the generic exemptions from authorisation can be applied. MSC notes that for such uses that fall under the generic exemptions from the authorisation requirement, there is no need to propose any additional specific exemptions.

[13] Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), dodecamethylcyclohexasiloxane (D6)

3.4.2 EXEMPTION REQUESTS SUBSTANTIATED BY REFERENCE TO SPECIFIC EU LEGISLATION

3.4.2.1 TERPHENYL, HYDROGENATED

MSC notes many exemption requests received from industry related exclusively to the uses of terphenyl, hydrogenated, as a heat transfer fluid in closed, tight systems at industrial sites operated under controlled conditions.

Some of the requests for exemptions for specific uses of terphenyl, hydrogenated, as heat transfer fluid under Article 58(2) of REACH were substantiated by reference to specific EU legislation or standards. Legislation or standards referred to in these requests included:

- Pressure equipment directive (97/23/EC)
- Technical directive on Heat-transfer systems with organic heat-transfer media - Operation, maintenance and repair (VDI 3033 guideline)
- Technical directive on Heat transfer installations working with organic heat transfer fluids (DIN 4754)
- National ordinances [Ordinance on industrial safety and health (BetrSichV), AD 2000 pressure vessel code, Ordinance on installations for handling substances hazardous to water (AwSV), Water resources act, German emissions law]

MSC notes that according to Article 58(2) of REACH, it is possible to exempt from the authorisation requirement uses or categories of uses 'provided that on the basis of the existing community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substances, the risk is properly controlled'.

Considering the requests above, MSC acknowledged the existence of EU legislation or standards applying to the uses of terphenyl, hydrogenated as a heat transfer fluid. However, MSC noted that with these exemption requests, no additional information on specific Community legislation imposing minimum requirements was provided to indicate that exemptions under Article 58(2) would be met. MSC also took into account 'ECHA's general responses on issues commonly raised in consultations on draft recommendations' and ECHA's previous responses to Article 58(2) exemption requests. MSC is of the opinion that exemptions under Article 58(2) are not warranted for terphenyl, hydrogenated.

3.4.2.2 SILOXANES

MSC notes that several comments received on siloxane substances request an exemption from authorisation referring to the upcoming restriction[14] proposed for D4/D5/D6 under REACH Annex XVII. As indicated in section 3.1.1.2 above, the aim of this upcoming restriction is to restrict D4, D5 and D6 in consumer and professional products. Some of the requests received are unspecific, stating that there must not be an overlap of regulations, i.e. better alignment between restriction and authorisation, and that uses derogated from restriction should be derogated from authorisation as well. MSC shares ECHA's view that authorisation and restriction can be used in a complementary manner and further, that uses of D4, D5 and D6 foreseen to be derogated from the upcoming

[14] https://echa.europa.eu/sk/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade

restriction in general fall within the scope of authorisation. Once included in Annex XIV, the substances will become subject to authorisation, unless they are generally exempted from authorisation requirement or a specific exemption is granted by the Commission pursuant to Article 58(2) of REACH.

There were also specific requests to exempt the placing on the market of D5 and D6 for use as medical devices, as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma. For D5 an exemption request for professional use in the cleaning or restoration of art and antiques was also made. It is argued by industry that these uses will be derogated from the upcoming REACH restriction based on sufficient information available to justify such derogation from the scope of the proposed restriction. MSC notes ECHA's view that, as these uses are derogated based on socio-economic considerations, conditions to fulfil the requirements of Article 58(2) appear not to be met.

Another specific request relates to the use of D5 in strictly controlled closed dry-cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated, which is foreseen to be exempted under the upcoming restriction under REACH Annex XVII. MSC notes ECHA's view that this use might be exempted on the basis of Article 58(2), provided that minimum requirements relating to the protection of human health or the environment are imposed.

Overall, MSC is of the opinion that there is currently no sufficient basis for recommending exemptions in Annex XIV for the siloxanes under Article 58(2) of REACH. MSC is of the opinion that as the restriction on D4, D5 and D6 is not yet adopted, it cannot be taken into account at this stage. MSC notes that ECHA refers to the European Commission who decides on the upcoming restriction of D4, D5 and D6, on the Annex XIV inclusion and considers whether conditions for an exemption under Article 58(2) of REACH could be met once this restriction is adopted. While MSC is of the opinion that the restriction cannot be taken into account at this stage, MSC would like ECHA to invite the European Commission to review the possibility for an exemption under Article 58(2) at the stage of drafting of, and discussions amongst REACH Committee experts on, the Annex XIV entry for the siloxanes, as the final scope of the restriction will be known at that stage.

3.4.3 EXEMPTION REQUESTS NOT SUBSTANTIATED BY REFERENCE TO SPECIFIC EU LEGISLATION

There were exemption requests for siloxane substances, terphenyl, hydrogenated, and dicyclohexyl phthalate which were not substantiated by reference to specific EU legislation. Across the different substances, these requests were based on issues such as documented and well controlled safe use compliant with different safety requirements, risk is properly controlled, use in strictly controlled closed system, no direct or negligible exposure to workers and environment and critical uses in certain sectors, like pharmaceutical industry or energy sectors. Some of the comments also pointed out the fact that currently no (safe) alternatives exist or that the alternatives themselves would have to fulfil safety requirements.

MSC considered all of these requests and is of the opinion that, while noting the points already made above, such exemptions are not warranted. MSC particularly referred to the information provided in ECHA's document on '*General responses on issues commonly raised in consultations on draft recommendations'* in forming its opinion in that regard.

3.5 EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

No exemptions for PPORD were proposed by ECHA. No requests for exemptions for PPORD were received during the consultation.

MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

3.6 OTHER ISSUES

For some of the prioritised substances, comments were raised during the consultation expressing concern that inclusion of the substances in Annex XIV would lead to socio-economic impacts in general, including a loss of competitiveness for certain European industries and negative effects on manufacturing processes in Europe.

Further comments referred to the European Green Deal and highlighted the importance of uses in products intended to reduce CO_2 emissions and their contributions to achieve the 2050 goals in carbon neutrality.

Comments were also received on some substances indicating that currently, no (safe) alternatives exist or emphasising difficulties on possible substitution.

MSC took note of these comments and is of the view that while these are valid issues, they do not affect the prioritisation of the substances for authorisation. MSC notes that these issues have been addressed previously in ECHA's '*General responses on issues commonly raised in consultations on draft recommendations'* and refers to the responses accordingly.

Therefore MSC concludes that these other issues do not affect the prioritisation of the substances in the draft 10th recommendation.

ECHA
EUROPEAN CHEMICALS AGENCY

ANNEX II

DRAFT TENTH RECOMMENDATION SUBMITTED FOR CONSULTATION ON ECHA WEBSITE

Draft 10th Recommendation of Priority Substances to be included in Annex XIV of 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	Octamethylcyclo tetrasiloxane (D4)	209-136-7	556-67-2	PBT (Article 57d), vPvB (Article 57e)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
2	Decamethylcyclo pentasiloxane (D5)	208-764-9	541-02-6	PBT (Article 57d), vPvB (Article 57e)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
3	Dodecamethylcyclo hexasiloxane (D6)	208-762-8	540-97-6	PBT (Article 57d), vPvB (Article 57e)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
4	Terphenyl, hydrogenated	262-967-7	61788-32-7	vPvB (Article 57e)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
5	Dicyclohexyl phthalate (DCHP)	201-545-9	84-61-7	Toxic for reproduction (Article 57c), Endocrine disrupting properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	Latest application date plus 18 months	None	None	None
6	Disodium octaborate	234-541-0	12008-41-2	Toxic for reproduction (Article 57c)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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**
7	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7	Respiratory sensitising properties (Article 57f – human health)	Date of inclusion in Annex XIV plus 18, 21 or 24 months	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.

** ECHA proposes to set the LADs within the range of 18, 21 or 24 months after the date of inclusion in Annex XIV. The specific LAD allocation will be done when finalising the recommendation. For this, ECHA will use all available relevant information including that received in the consultation. ECHA's recommendation for specific LAD slots will be based on the *General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV*[15] and as further specified in the *practical implementation document*[16]. Substances considered as a group will be allocated to the same slot.

[15] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[16] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf