**Comments on the draft scientific dossier in accordance with Annex D to the Stockholm Convention that is intended to accompany an EU proposal for listing octamethylcyclotetrasiloxane (D4); decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6) under the Convention**

|  |  |
| --- | --- |
| **Substance name:** | Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6) |
| **CAS number:** | 556-67-2, 541-02-6, 540-97-6 |
| **EC number:** | 209-136-7, 208-764-9, 208-762-8 |

Start date of the consultation: 15/06/2023

End date of the consultation: 10/08/2023

Scope: Draft scientific dossier (Annex D) for an EU proposal for the listing of D4, D5 and D6 in Annex B to the Convention

Disclaimer: Comments provided during the consultation are made available in this document as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information.

|  |  |  |
| --- | --- | --- |
| **Comment number/Date** | **Submitted by** | **Comments** |
| **28**  **Date:**  2023/07/03 16:18 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Moroccanoil  **Org. country:**  Germany | **General Comments:**  Hi I would like to ask to exclude Decamethylcyclopentasiloxane (D5) from this amendment for its vast use in the personal industry and due o the fact that it is not as harming as Octamethylcyclotetrasiloxane (D4). I dont think both should be treated the same. Also, if this new amendment comes in to force i would to ask for a 5 year transition for Leave on cosmetic products.  Yhank ou Idan |

|  |  |  |
| --- | --- | --- |
| **29**  **Date:**  2023/07/11 19:37 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  GreenEarth Cleaning  **Org. country:**  United States of America  **Attachment:**    **Privacy comment:**  Thank you for the opportunity to comment on this proposal. | **General Comments:**  Thank you for the opportunity to comment on this proposal. |

|  |  |  |
| --- | --- | --- |
| **30**  **Date:**  2023/07/13 16:25 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  European Semiconductor Industry Association (ESIA)  **Org. country:**  Belgium  **Attachment:** | **General Comments:**  Please see the attachment. |

|  |  |  |
| --- | --- | --- |
| **31**  **Date:**  2023/07/18 10:51 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  <redacted>  **Org. country:**  Germany  **Attachment:**  <redacted>  **Privacy comment:**  The defence industry is still accepted in full despite the change in global political situation. Thus open statements are allowed by company policy | **General Comments:**  Please see attached pdf |

|  |  |  |
| --- | --- | --- |
| **32**  **Date:**  2023/07/21 17:09 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  GIFAS  **Org. country:**  France  **Attachment:** | **General Comments:**  Subject : D4/D5/D6 substances for aeronautics, space and defence applications Ref: Consultation-Proposals for new POPs  On 15th June 2023, the European Chemicals Agency (ECHA) launched a consultation for the potential proposal of the European Commission to nominate: - Octamethylcyclotetrasiloxane (D4)- CAS n° 556-67-2, - Decamethylcyclopentasiloxane (D5)- CAS n° 541-02-6, - Dodecamethylcyclohexasiloxane (D6)- CAS n° 540-97-6, for inclusion in the Stockholm Convention as Persistent Organic Pollutants (POPs) substances.  This paper constitutes the GIFAS (French aerospace industries association)\* position.  Silicone polymers rely on D4, D5 and D6 for their manufacturing and their use in a variety of sectors such as construction, automotive, electronics, pulp and paper, oil and gas, medical and aerospace/defence. These polymers have currently wide applications within the Aerospace and Defence industry. They are present primarily in adhesives, sealants, fire resistant void fillers and potting compounds, but also in finished articles made of silicone rubber, and help to provide a set of unique properties which, as research has so far indicated, cannot be achieved by any other chemistry. The concentrations of D4 and/or D5 and/or D6 in the final products e.g silicone sealants and adhesives are usually very low (around 0.1%) and considered as traces (unreacted monomers). Their use in the electronics sector is also significant, as silicone coatings protect sensitive components from moisture, dirt, shocks and vibrations and can withstand extreme temperatures without losing their properties.  D4, D5 and D6 have been identified in the EU under REACH as Substances of Very High Concern (SVHC) and included in the Candidate List for Authorisation in June 2018. Furthermore, the use of D4 and D5 in wash-off cosmetic products has been restricted in the EU under the REACH Regulation since 31st January 2020 and another REACH restriction for D4, D5 and D6 in consumer and professional products is under review by the European Commission. The vast majority of the environmental emissions of these substances come from the area of personal care products.  We would like to highlight our full commitment to improve the protection of human health and the environment from the risks that can be posed by hazardous chemicals and our industry has been working for years towards a voluntary eradication of many of the most hazardous substances. In parallel, our industry is also fully committed to ensure safety and reliability of the aerospace and defence systems and their repair and maintenance all along their lifecycle. Implementing an alternative solution requires stringent, long and intensive testing for qualification (reliability, test programmes). The implementation of the substitution roadmaps must be carefully, progressively and sequentially made, on a step-by-step approach, once alternatives are validated to ensure relevant lessons are learned prior to generalisation. Silicone materials are difficult to substitute because of their durable, safe and highly effective mechanical, optical and thermal properties.  Our industry supports an effective and proportionate approach to managing the risks associated with these substances. Whilst waiting for the current REACH restrictions to be adopted and evaluated at EU level, we believe that launching new regulatory projects should be avoided to prevent any overlap or conflict with the existing proposed approach in terms of restriction.  With regards to the implementation of the Stockholm Convention in the EU, the potential inclusion of D4, D5 and D6 in the EU POPs regulation would affect the trade, production, and accessibility of silicones across the globe and hamper the ability of EU downstream users to access silicones. Ultimately, this would hamper value chains established in Europe, in favour of other regions where the access is secured in a timely and affordable manner.  Before any proposal is presented, the European Commission should: - Consider all the available scientific information to understand whether D4/D5/D6 meet the criteria of Persistent Organic Pollutants (POPs) under the Stockholm Convention; - Address the technical, legal, socio-economic aspects of a listing of D4/D5/D6 under the Stockholm Conventions as well as any direct and indirect consequences that such a listing would have on silicone manufacturers and downstream users; - Implement existing or proposed regulatory measures and assess their efficiency, in particular the REACH restriction.  We therefore ask the European Commission not to propose designating D4/D5/D6 as POPs under the Stockholm Convention until all these conditions have been met, in order to avoid risks disrupting the silicones value chain in Europe.   (\*) GIFAS (French aerospace industries association) has more than 450 members, from major prime contractors and system suppliers to small specialist companies and start-ups. They cover the full spectrum of skills from the design, development and production of aerospace systems to marketing and maintenance and operation. GIFAS members are active in all sectors of the aerospace industry including civil and military aircraft, helicopters, engines, missiles and weapons, satellites and launch systems, UAV, large aerospace, defence and security systems, equipment, subassemblies and associated software applications. Turnover for the French Aeronautical, Space, Defence and Security Industry: €62,7 billion in 2022; Export: 83%; 195.000 direct employees. |

|  |  |  |
| --- | --- | --- |
| **33**  **Date:**  2023/07/23 21:39 | **Type:**  Individual  **Country:**  United Kingdom  **Attachment:** | **General Comments:**  The attached comments have been compiled by Professor Mick Whelan from the University of Leicester, UK and Dr Todd Gouin, an independent consultant which substantial experience in evaluating the fate and transport of environmental contaminants. Whelan has had a close interest in the environmental fate of VMS for the last 20 years and has co-authored several papers in the scientific literature on aspects of their behaviour in air, water, sediment and in food webs. Gouin has also published widely in this field, including on cVMS behaviour. Although both Whelan and Gouin have collaborated actively with industry, the attached observations are submitted independently. In general, we applaud ECHA for pulling together such a detailed synthesis of cVMS properties and data. However, we think that some of the interpretations could be better-justified. Whilst D4, D5 and D6 appear to satisfy the criteria for persistence (e.g. in sediment), relatively rapid environmental loss processes (hydrolysis and atmospheric reaction) and inter-media transfers mean that overall longevity is likely to be much lower than that for most classical POPs. Similarly, cVMS compounds appear to meet the criteria for bioaccumulation potential (although this is tempered to some extent by metabolism and other clearance processes in many organisms – such as partitioning to air in air-breathing animals). With respect to long-range transport, it is clear that cVMS compounds are transported over long distances in the air. However, in our opinion, the evidence base for deposition to surface media in high latitudes is weak and should be strengthened by additional monitoring, experimental studies and modelling. Whilst the postulated deposition mechanisms will all operate to some extent, the magnitude of these processes is highly uncertain and the conclusions are, therefore, speculative. |

|  |  |  |
| --- | --- | --- |
| **34**  **Date:**  2023/07/25 22:04 | **Type:**  Individual  **Country:**  United States of America  **Attachment:** | **General Comments:**  none |

|  |  |  |
| --- | --- | --- |
| **35**  **Date:**  2023/07/26 11:49 | **Type:**  Individual  **Country:**  Germany  **Attachment:**    **Privacy comment:**  References Most papers must follow the copyright laws given by the journal. | **General Comments:**  References: Pauluhn, J., Hahn, A. and Spielmann, H. (2008). Assessment of early acute lung injury in rats exposed to aerosols of consumer products: attempt to disentangle the ‘magic nano’ conundrum. Inhalation Toxicology 20:1-18. Pauluhn, J. , 2021. Phosgene Inhalation Toxicity: Update on Mechanisms and Mechanism-Based Treatment Strategies. Toxicology 28;450:152682. doi: 10.1016/j.tox.2021.152682. Epub 2021 Jan 20. Pauluhn J., 2021. Toxicokinetic Tests. In: Reichl FX., Schwenk M. (eds) Regulatory Toxicology. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-36206-4\_38-2 Pauluhn J, 2021. Inhalation toxicity of cyclic semi-volatile methylsiloxanes: Disentangling the conundrum of phase-specific adaptations from adverse outcomes. Regul Toxicol Pharmacol. 122:104923. doi: 10.1016/j.yrtph.2021.104923. 178. Pauluhn J, Whalan JE, 2021. Human Risk Assessment of Inhaled Irritants: Role of Sensory Stimu¬la¬tions from Spatially separated Nociceptors. Toxicology. Sep 2:152929. doi: 10.1016/j.tox.2021.152929. 179. Pauluhn J., 2022. Derivation of Thresholds for Inhaled Chemically Reactive Irritants: Searching for Substance-Specific Common Denominators for Read-Across Prediction. Regul Toxicol Pharmacol. https://doi.org/10.1016/j.yrtph.2022.105131 180. Pauluhn J., 2023. Pathogenetic role of alveolar surfactant depleted by phosgene: Biophysical mechanisms and peak inhalation exposure metrics. Regul Toxicol Pharmacol. 143, 105441. |

|  |  |  |
| --- | --- | --- |
| **36**  **Date:**  2023/07/26 18:27 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Claigan Enviromental Inc.  **Org. country:**  Canada | **General Comments:**  We are a high volume test laboratory for physical products (articles). We have been tested components in articles for D4, D5, and D6 since 2018.  For the past 1,000 components silicone rubber components (in articles) tested a). 30% contained D6 above 100 ppm b). Of D6 detected, the average value in silicone rubber components in articles was ~300 ppm c). The 95 percentile value in finished silicone was ~800 ppm d). The maximum measured value in finished silicone was ~1,500 ppm  The present of D6 (and D4 and D5) is related to cured silicone. In the uncured form, the silicone rubber contains between 0.5% to 1% D6 (as listed on the safety data sheet in the uncured form). The concentration of final article is related to the quality of the curing process. Longer and more effective curing processes result in lower D6 concentrations in the final article.  If D4, D5, and D6 were restricted in the future, a limit of 1,000 ppm would be reasonable for real world situations. By managing the curing process, D4, D5, and D6 can be maintained below 1,000 ppm.  Note - D6 containing silicone is one of the main replacements for PFAS polymers. If D6 is highly regulated, then even further derogations will be needed for the REACH PFAS Regulation. However, the average silicone contains roughly 1,000X higher concentration of forever chemicals (D6) than typical PFAS polymers such as PTFE (with less than 1 ppm PFOA - and only contain PFOA if irradiated). Regulation of D6 makes more sense than regulation of unirradiated PTFE. |

|  |  |  |
| --- | --- | --- |
| **37**  **Date:**  2023/07/27 19:21 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  Dear Sir/Madam, The ownership of the attached study reports is within the Members of the Reconsile REACH Consortium, therefore the enclosed study reports can be used by ECHA for assessment purposes only and shall not be published in any form, including on the ECHA website. Kind regards, Valentina Cupella | **General Comments:**  Dear Sir/Madam,  The ownership of the attached study reports is within the Members of the Reconsile REACH Consortium, therefore the enclosed study reports can be used by ECHA for assessment purposes only and shall not be published in any form, including on the ECHA website.  Kind regards, Valentina Cupella |

|  |  |  |
| --- | --- | --- |
| **38**  **Date:**  2023/07/28 12:03 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  GlobalFoundries  **Org. country:**  Germany  **Attachment:**  <redacted>  **Privacy comment:**  Protection of our IP to safeguard commercial interests. | **General Comments:**  Please see general comments in the confidential attachment. |

|  |  |  |
| --- | --- | --- |
| **39**  **Date:**  2023/07/31 04:56 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Electronics and Information Technology Industries Association (JEITA)  **Org. country:**  Japan | **General Comments:**  We, Japanese electric and electronic industrial associations : JEITA (Japan Electronics and Information Technology Industries Association); CIAJ (Communications and Information Network Association of Japan); JBMIA (Japan Business Machine and Information System Industries Association); and JEMA (Japan Electrical Manufacturers’ Association) have been vigorously committed to improving environment and to complying with chemical regulations set by EU and other countries including the U.S. and China, etc. The electrical and electronic equipment (EEE) are manufactured via supply-chain extending over the world, and chemical legislations under POPs Convention would have big influence over the world. Therefore, we would like to input our view as EEE manufacturers though we don't have much information on D4, D5 or D6.  (1)　As long as we know, neither D4, D5 nor D6 is directly used in EEE. We have shared the information on this consultation with our members and asked for their knowledge on these substances, but no input came regarding applications of D4, D5 and/or D6 in our industry. Consequently, we recognise that D4, D5 and/or D6 on its own or in mixtures is not added to EEE, and as the result, we don’t have any information for other concrete questions. (2)　On the other hand, according to our suppliers’ industry, silicon polymers made from raw materials including D4, D5 and/or D6 (especially D4) are widely used in parts of EEE or material of them and those are also indispensable. Silicone Industry Association explains for us that these substances cannot be substituted as basic raw materials of silicone. (3) We are seriously concerned that POPs nomination of D4, D5, and D6 will lead to strict restrictions on the production, use, and trade of silicone polymers. We use silicone products for critical applications in Electronics and Information industries to secure the reliability and safety of products. The nomination will bring a significant negative impact on industries and society. Even if the nomination intent is to exempt polymer use, no one cannot control the scope of the regulation once the nomination is proposed to POPRC. We are afraid that the scope of POPs nomination of D4, D5, and D6 would be much broader than the current and the planned restriction of those substances in EU. D4, D5, and D6 were assessed in Canada, Australia and Japan, and no use restriction was set in those countries. We would like to request EU Commission and ECHA to assess them more carefully.  About Japanese electric and electronic (E&E) industrial associations: About JEITA: The objective of the Japan Electronics and Information Technology Industries Association (JEITA) is to promote the healthy manufacturing, international trade and consumption of electronics products and components in order to contribute to the overall development of the electronics and information technology (IT) industries, and thereby further Japan's economic development and cultural prosperity.  About CIAJ: Mission of Communications and Information network Association of Japan (CIAJ). With the cooperation of member companies, CIAJ is committed to the healthy development of info-communication network industries through the promotion of info-communication technologies (ICT), and contributes to the realization of more enriched lives in Japan as well as the global community by supporting widespread and advanced uses of information in socio-economic and cultural activities.  About JBMIA: Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.  About JEMA: The Japan Electrical Manufacturers' Association (JEMA) consists of major Japanese companies in the electrical industry including: power & industrial systems, home appliances and related industries. The products handled by JEMA cover a wide spectrum; from boilers and turbines for power generation to home electrical appliances. Membership of 291 companies, http://www.jema-net.or.jp/English/ |

|  |  |  |
| --- | --- | --- |
| **40**  **Date:**  2023/07/31 08:05 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Auto Parts Industries Association  **Org. country:**  Japan | **General Comments:**  We, JAPIA, oppose the nomination of D4, D5 and D6 to the Stockholm convention. We would like to discuss the impact of listing D4, D5 and D6 in POPs. The automobile parts industry relies on a wide variety of chemicals and materials to create vehicles that meet the highest standards of quality, safety and environmental performance. D4, D5 and D6 are used to make silicone polymers (\*) that play an important role in automotive manufacturing, ensuring the reliability and longevity of automotive parts. (\* silicone polymers : including silicone resin, rubber, oil, varnish, etc.) Heat resistance, weather resistance, chemical stability, electrical insulation, water repellency, mold releasability, cold resistance, and low temperature dependence of silicone polymers are essential properties for establishing the basic performance of automobiles. For example, silicone materials are indispensable in areas where heat resistance and chemical stability are required, such as seals around engines. Furthermore, taking advantage of its high heat dissipation, it is widely used in electric vehicle power control units, lithium-ion batteries, power devices, and the like. This makes a great contribution to the reduction of CO2 emissions from automobiles. It is also used for various sensors, taking advantage of its cold resistance and oil resistance. This ensures safe driving. In this way, silicone has become an indispensable material for establishing the basic performance of automobiles. There is one thing that worries us about the nomination for the Stockholm Convention. Even if it is nominated under Annex B (restriction), it may be listed under the Stockholm Convention under Annex A (prohibited). The current POPRC and COP are often politically rather than scientifically based discussions. Furthermore, what should be discussed on a risk basis may proceed on a hazard basis. Considering it, we think that D4, D5 and D6 should not be nominated for the current Stockholm Convention. Furthermore, the long-distance mobility described in this Annex has not been peer-reviewed, and its veracity is open to debate. Considering this, I think it is necessary to wait for the results of the observations in Antarctica that are currently being prepared and reconsider the discussion. If D4, D5 and D6 become regulated under the Stockholm Convention, it could result in severe restrictions on the manufacture, use and trade of silicone polymers. Imposing such restrictions would have serious consequences for the automotive industry. Furthermore, it will hinder the innovation and development of cleaner and more sustainable vehicles, which are essential to achieving the EU's climate and carbon neutrality goals For these reasons, we, JAPIA, oppose the nomination of D4, D5 and D6 to the Stockholm convention. |

|  |  |  |
| --- | --- | --- |
| **41**  **Date:**  2023/08/01 11:44 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Spain  **Attachment:**  <redacted>  **Privacy comment:**  See attached document for details | **General Comments:**  Confidential information provided in section V. |

|  |  |  |
| --- | --- | --- |
| **42**  **Date:**  2023/08/01 11:53 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Spain | **General Comments:**  Germaine de Capuccini has been dedicated to professional aesthetics for more than 50 years, with the same values as when we started: professionalism, innovation and social commitment to women. Its mission is to make the best treatments and products available to the expert hands, all over the world, of those who best know the needs of your skin: beauticians. Passionate and curious, always in continuous evolution, to develop the most avant-garde treatments with beautifying results for the skin. EXPERT HANDS: Their application methods are unique and exclusive. Through training we make our value reach all the Germaine Centers around the world. INNOVATION: An own laboratory where unique formulas and advanced technology are created that freeze time to offer a sublime experience. Research and quality are considered the key, therefore, they invest time and resources in developing perfect formulas. Our investment in R&D is above the European average, according to data from Stanpa. For every skin need, Germaine de Capuccini has effective and sensorial treatments in the cabin, which are applied through specific maneuvers and treatments for use at home. For Germaine de Capuccini silicones are ingredients widely used in personal-care products. They are one of the few ingredients commonly used in formulations that can create a “wow factor,” or a readily noticeable sensory effect. Besides the basic cosmetic products, silicones are used extensively in OTC and sensitive skin products due to their non-irritating characteristics. Silicones are also not animal derived and therefore approved by Vegans as cruelty free materials. They are not related to palm and RSPO issues and are certified as GMO free. The types of silicones used in cosmetic products are supported by scientific research and are considered extremely safe for consumer use. Silicones are effective, inert, and versatile ingredients that benefit skin and hair in numerous ways.  Silicone is added to cosmetic products due to the following functions. - Emulsification: Combines with other ingredients. - Emollient: Softens and smoothens the skin surface. - Surfactant: Better application of the product.  Silicones are an essential part of Germaine de Capuccini’s business as they provide benefits that impact the performance of almost every type of beauty product, conferring attributes such as good spreading, film forming, wash-off resistance, skin feel, volatility and permeability. These versatile materials improve the performance of many cosmetics, sunscreens and skin treatment products. They help deliver pigments and other particles to the skin, enhance protection by sunscreens and improve the stability of antiaging ingredients.  Silicones are introduced in formulas in order to perform the specific role expected of them like waterproofing, retaining moisture, adhering colour pigments, protecting our hair and imparting smoothness, and making the application of skincare products feel silky i.e. no tugging on the skin as it is spread on, and no oily, sticky feeling. They keep water-resistant sunscreens on our skin, even when we sweat or get wet.  Silicones have revolutionized the application and longevity of most makeup products, including BB and CC creams. Silicones are critical in many foundation formulations to give them more ‘spreadability’ and a luxurious, comfortable feel on skin. Silicones are used to increase water resistance in a formula. This is particularly useful for sun-protection products, foundations and powders, especially those that make the claim of being water-resistant and waterproof.  In the cosmetic industry, silicones and silicone derivatives mainly act as emollients, humectants, surfactants (emulsifiers), and film formers, antifoaming, viscosity-controlling agents, antistatic and binding agents. Silicones are used in a widely portfolio of products. In our case specifically for hair care products, sunscreen products, decorative cosmetics and skincare products which means a mean of 250.000€ spent annually (data from 2022).  The benefits of using silicones in cosmetic industries are: 1) Improves the Texture of the Skin: Silicone provides a non-sticky, matte finish to the skin. It makes the product sweatproof and waterproof and allows the product to stay on the skin for a long time. It hydrates the skin and gives a smooth finish to the skin devoid of fine lines and wrinkles. It improves skin elasticity and strength by stimulating the fibroblasts to produce more collagen. 2) Locks the Moisture Content: When silicone-containing products are applied to the skin, it forms a layer that acts as a barrier to prevent water loss. It keeps the skin well-nourished and hydrated. It acts as a vehicle for the delivery of the key ingredients in the product. 3)Improves the Consistency of the Product: When silicone is added as one of the ingredients in the product, it acts as a hydrating agent, blends with other ingredients, and makes the product spreadable in consistency.  At the bench chemist level, they allow the development of innovative formulations for foundations and sun care products, permitting the delivery of actives while maintaining very good sensory profiles. Taking in consideration that the sector in EU directly employs more than 197,000 people and it is estimated that it does so indirectly to more than 1.63 million people (trade, hairdressing and beauty salons, demopharmacy, transport, advertising, etc.); the elimination of silicones would imply a halt in the development of the sector.  - Germaine de Capuccini strongly believes that the recent European Commission’s proposal to nominate D4, D5 and D6 under Annex B to the Stockholm Convention on Persistent Organic Pollutants does not take full account of the whole body of scientific evidence, should have recognised already applicable or on-going regulatory activities, and puts at risk numerous beneficial uses including in the cosmetic industry sector. - Silicone polymers rely on D4, D5 and D6 as building blocks (monomers) for their manufacturing. Silicone materials are widely used and difficult to substitute because of their durable, safe and highly effective mechanical, optical and thermal properties. - Silicones are essential to build a green value chain in Europe, in light with the EU Green Deal objectives and strategic autonomy. - When it comes to the implementation of the Stockholm Convention in the EU, the potential inclusion of D4/5/6 in the EU POPs regulation would affect the trade, production, and accessibility of silicones across the globe and hamper the ability of EU downstream users to access silicones. Ultimately, this would hamper value chains established in Europe, in favour of other regions where the access is secured in a timely and affordable manner. - Before any proposal is presented to the Council of the European Union, the European Commission shall: - Consider all the available scientific information to understand whether D4/D5/D6 meet the criteria of Persistent Organic Pollutants under the Stockholm Convention. - Address the technical, legal, socio-economic aspects of a listing of D4/D5/D6 under the Stockholm Conventions as well as any direct and indirect consequences that such a listing would have on silicone manufactures and downstream users.  We call on the European Commission to recall their proposal to nominate D4/5/6 as POPs under the Stockholm Convention, before a thoughtful legal, technical, socio-economic and scientific assessment is in place. Germaine de Capuccini stands ready to work with its silicone suppliers and regulatory authorities to ensure that silicones polymers can continue to be used and their innovation potential preserved. |

|  |  |  |
| --- | --- | --- |
| **43**  **Date:**  2023/08/03 15:07 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Hermann Otto GmbH  **Org. country:**  Germany | **General Comments:**  - Hermann Otto GmbH (OTTO-CHEMIE) is a medium-sized manufacturer of adhesives and sealants. OTTO-CHEMIE achieves a turnover of about 160 million € with about 500 employees. 80 % of sales are generated with silicone adhesives and sealants. - OTTO-CHEMIE is a so-called formulator/compounder of silicon adhesives and sealants. As an industrial downstream user, we produce silicone adhesives and sealants for the construction industry and special industries such as renewable energies and household appliances. We use silicone polymers made from cyclic siloxanes to produce our adhesives and sealants. - Silicones are characterised by exceptional resistance to ageing and weathering as well as extreme temperature resistance. For this reason, silicones are predestined for applications such as the bonding and sealing of photovoltaic modules and hot water collectors. Components of household appliances are bonded and sealed with silicones due to the very high temperature resistance of silicones. Silicone sealants are used in the construction industry as highly elastic sealing material for facades, window and door sealing. Silicones make an important contribution to increasing the energy efficiency of buildings and thus achieving the goals of the European Green Deal. - OTTO-CHEMIE as an industrial downstream user providing silicone sealants and depends on the availability of silicone polymers in Europe as well as the legal authorisation to use those polymers in its products.  OTTO statement: For OTTO-CHEMIE it remains unclear which consequences are to be expected if the cyclic siloxanes D4 D5 D6 are added to Annex B under the Stockholm Convention. It is to expect that a restricted usage of silicone polymers as feedstock for silicone products risks disrupting the silicones value chain in Europe. As consequence it would undermine efforts to achieve the goals of the European Green Deal, where silicone products contribute to in various applications.  - OTTO-CHEMIE strongly believes that the recent European Commission’s proposal to nominate D4, D5 and D6 under Annex B to the Stockholm Convention on Persistent Organic Pollutants does not take full account of the whole body of scientific evidence and puts at risk numerous beneficial uses of silicones e.g., in the construction, alternative energy and electronics sector. - Silicone polymers rely on D4, D5 and D6 as building blocks (monomers) for their manufacturing. Silicone materials are widely used and difficult to substitute because of their durable, safe and highly effective mechanical, optical and thermal properties. - Silicones are essential to build a green value chain in Europe, in light with the EU Green Deal objectives and strategic autonomy. - When it comes to the implementation of the Stockholm Convention in the EU, the potential inclusion of D4/5/6 in the EU POPs regulation would affect the trade, production, and accessibility of silicones across the globe and hamper the ability of EU downstream users to access silicones. Ultimately, this would hamper value chains established in Europe, in favour of other regions where the access is secured in a timely and affordable manner. - Before any proposal is presented to the Council of the European Union, the European Commission shall: - Consider all the available scientific information to understand whether D4/D5/D6 meet the criteria of Persistent Organic Pollutants under the Stockholm Convention. - Address the technical, legal, socio-economic aspects of a listing of D4/D5/D6 under the Stockholm Conventions as well as any direct and indirect consequences that such a listing would have on silicone manufactures and downstream users. We call on the European Commission to recall their proposal to nominate D4/5/6 as POPs under the Stockholm Convention, before a thoughtful legal, technical, socio-economic and scientific assessment is in place.  OTTO-CHEMIE stands ready to work with its silicone suppliers and regulatory authorities to ensure that silicones polymers can continue to be used and their innovation potential preserved. |

|  |  |  |
| --- | --- | --- |
| **44**  **Date:**  2023/08/04 13:05 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Silicones Europe, a sector group of Cefic  **Org. country:**  Belgium  **Attachment:** | **General Comments:**  Silicones Europe welcomes the opportunity to provide comments in the public consultation on the “Draft proposal to list D4, D5 and D6 in Annex B to the Stockholm Convention on Persistent Organic Pollutants” (POP).  Silicones Europe, a sector group of Cefic, is a non-profit trade organisation representing all major producers of silicones and silanes in Europe (CHT, Dow, Elkem, Evonik, Momentive, Shin-Etsu, Wacker). The European Silicones industry employs more than 8,000 people, producing 617,000+ tonnes of formulated silicone products and generates over 3.5 billion euros in annual sales. Sales of final products containing silicones amount to around 10 billion euros per year, a value generated by 1.4 million people employed across the downstream value chain (data from 2018, excluding CHT).  D4, D5 and D6 are crucial monomer intermediates used in the manufacturing of silicone polymers, representing the vast majority of their uses. If silicone monomers are nominated for a POP listing, this would be the first time that the Stockholm Convention has been proposed as a tool to regulate intermediates. The silicones industry believes that this would endanger the manufacture and use of silicone polymers, materials that are pivotal to society and for the success of the European Green Deal, as well as the ‘twin’ green and digital transitions of the European economy.  During the POP CA meeting, the European Commission indicated orally its aim to “protect” silicone polymers from indirect impact due to global restrictions on D4, D5, D6 that would follow the listing of these substances. We understand from the Commission that this would be achieved by allowing the continued use of D4, D5 and D6 for the manufacture and use in silicone polymers´ production through an acceptable purpose exemption as transported intermediates, and an exemption for closed-system site-limited intermediates. The Commission also confirmed that the final decision on such derogations would be made on a global level and no guarantee can be provided that the intended “protection” for polymers can be achieved.  Direct uses represent only a minor application of D4, D5 and D6, amounting to less than 2% of global production. Hence, such a ‘broad acceptable purpose’ would apply to more than 98% of the uses of these substances, an approach for which there are no precedents. A POP listing would not be the right tool to globalise the REACH restrictions and would instead put at risk silicone polymers and their many key applications. In contrast, other existing, more targeted, regulatory tools would allow to address concerns from direct uses with no impact on silicone polymers.  Following a POP listing, the production of silicone polymers would also be negatively impacted by severe restrictions on the on-site industrial use of D4, D5 and D6 as intermediates and on their presence as residues in polymers. The Stockholm Convention does provide exemptions for on-site intermediate use and residues. However, the text of the Convention does not give a clear definition of the required conditions under which intermediate use is exempted, nor it does specify allowed concentration limits for residues, all of which is left to the interpretation of individual Parties. Without an unequivocal definition at UN level of these aspects, differences in implementation would create distortions in the market for silicone polymers, which would be subject to different rules across different countries.  Listing D4, D5 and D6 under the Stockholm Convention would also have a negative impact on recycling and circularity. Severe restrictions are placed on the recycling of waste containing POP substances. Under a POP listing scenario, if “allowed” concentrations of POP content in waste were to be set at an unworkable value, all waste containing silicone polymers generated from D4, D5 and D6 would have to go to incineration. This would contradict the EU circular economy objective of increasing recycling rates. Also, D4, D5 and D6 – if listed as POPs – could not be recycled.  Furthermore, a POP listing would create an unlevel global playing field, as the provisions of the Stockholm Convention would not apply in countries which are not a Party, such as the United States, or could be implemented less diligently than in the EU. This would lead to increase of investments in other regions, to the detriment of Europe’s competitiveness and strategic autonomy.  Finally, the silicones industry believes the scientific criteria for a nomination under the Stockholm Convention are not fulfilled. Please see detailed comments on the ECHA technical dossier in our separate input to this consultation. Before proposing a POP listing for D4, D5 and D6, uncertainties in the scientific community should be resolved.  In sum, the Stockholm Convention is neither the right policy tool nor will it achieve the desired effect of addressing concerns regarding personal care products at the global level and simultaneously protect silicone polymers. In light of the significant socioeconomic impact that would result from the non-availability of silicone polymers, Silicones Europe asks that a detailed legal and impact assessment is carried out before proceeding onto a POP listing proposal for D4, D5 and D6.  We invite you to further explore the extent of these issues in our submission to this consultation, and we would welcome the opportunity for further discussion in order to answer any supplementary questions you might have. |

|  |  |  |
| --- | --- | --- |
| **45**  **Date:**  2023/08/04 16:40 | **Type:**  Individual  **Country:**  Canada | **General Comments:**  Department of Chemistry McMaster University 1280 Main St. W., Hamilton, Ontario, Canada, L8S 4M1. E-Mail: mabrook@mcmaster.ca Aug. 4, 2023  RE: Consideration of silicone cyclics as targets for POP  ECHA – European Chemicals Agency P.O. Box 400, FI-00121 Helsinki, Finland  To Whom It May Concern:  The declaration of POP for a specific compound must pass a high barrier, as once so listed, many other significant consequences follow.  Compounds that are POP should normally be ones for which thermodynamic properties are disadvantageous to spontaneous degradation. Such a situation occurs when bond strengths are very high, compared to the normal oxidative mechanisms on the planet. For example, C-F is a much stronger bond than C-O, such that unusual processes will be required for the compound to metabolize biologically or environmentally. Additionally, for compounds to be considered for POP there must be a kinetic impediment, that is, they CANNOT undergo facile degradation once entering the environment. If convenient, facile, energy available mechanisms are available to convert the compound in question to benign compounds via environmental or microbial processes they should not be eligible for POP status. By contrast, if there is no straightforward degradation mechanism, the compound will be sequestered in the environment and unable to degrade. Note that, in addition to chemical processes, kinetic requirements can include solubilization. For example, PCBs are extremely low surface energy materials that are nearly insoluble in water, which makes reactions with them in the environment difficult. It is not acceptable to use simplistic parameters, e.g., Kow, to make data driven decisions about POP, based simply on hydrophobicity particularly when other, compelling, excellent data is available.  Silicones, including small molecules D4, D5, and D6 (cyclics) do not fit the requirements for POP listed above. The element silicon is at its most thermodynamically stable form on this planet when bonded to oxygen atoms, as is the case with silica and silicates (note that even fluorosilicates, with stronger Si-F than SiO bonds undergo defluorinative degradation in the environment). The bond strengths of both Si C and C-H bonds (the other constituents of silicones, methyl groups) are lower than Si-O, by a lot. There is thus a strong thermodynamic advantage of cyclics and other silicones to be converted back to sand rather than being marooned in the environment.  Kinetic pathways for degradation are well established for cyclics. In the air compartment, oxidative degradation by hydroxy radicals initiates a cascade of radical reactions – a series of kinetically viable mechanisms - that convert cyclics to sand. The same processes occur on the surface of land. The fallacy of Kow as a guidance for POP is demonstrated with silicones. All silicones, including cyclics, are at a thermodynamic advantage when at an air interface. Therefore, in the liquid state (their normal state at ambient temperatures) they spontaneously spread across available media to make new interfaces with air. Such migration to air interfaces can occur from beneath the soil surface, delivering the cyclic to water compartment/land compartment air interfaces where degradation, or migration to the air compartment, can occur. Thus, their very low solubility in water DOES NOT CORRELATE WITH AN INABILITY TO ENVIRONMENTALLY DEGRADE: cyclics are shown to efficiently migrate to air interfaces and degrade through facile oxidative processes to more thermodynamically stable products.  Biological mechanisms to oxidatively degrade cyclics have also been demonstrated to occur by microbes and, rare for any synthetic chemical compound that is not a pharmaceutical, in mammals. When exposed to high air concentrations of D4 in air, mammals sequester much of it in the liver. However, once back in unsaturated air the animals, including humans, mostly respire the D4 out. A small fraction, however, is oxidized like any fat in the liver. The metabolites are analogous to those found in the hydroxy radical oxidation pathway, with cleavage of both Si-O and Si-C bonds. These declarations about the chemical reactivity of cyclics are backed by extensive peer reviewed literature and data acquired by silicone producers.  Thus, the physical chemistry and reactive chemistry characteristics of cyclic silicones on this planet do not fit the requirements for POP.  Unintended consequences It is my opinion that statements suggesting, “Restrictions on cyclics won’t extend to silicone polymers,” are disingenuous. Should the cyclics be declared POP, the entire silicone industry runs the risk of being put out of business because it is not possible to prepare silicone polymers that don’t contain, at least, very small quantities of cyclics. The implications of removing silicones from the marketplace are significant and very negative on many levels.  There are industries where silicone polymers, arguably, deliver real benefit/value to customers but are not required; other, poorer performing materials can be used as replacements. However, many other applications are critical for patients and materials to replace silicones do not exist. These include, but are not limited to: the best electrically resistant and biologically resistant coatings on pacemaker leads, the best needle lubricants for delivering protein-based drugs from glass syringes, the best topical adhesives for wound dressings and topical drug delivery, and the best catheters – e.g., Foley catheter. Silicones are intrinsic to the practice of safe medicine. They are transparent, which facilitates following the patient, induce an exceptionally weak foreign body response, but not an immunological response, and are readily sterilized by a variety of means including EO, autoclave, irradiation. Other materials don’t deliver.  Silicones are deeply embedded into technologies across multiple fields, including electronics (displays, phones, etc.), spark plug wires, photocopy machines, flame resistant foams for transportation applications, optical devices (LEDs), to name a few. Other materials do not possess the thermal or electrical (voltage/current) stability. Thus, we risk affecting many of the technological developments upon which we rely.  More problematic losses would be the uses of SILICONES THAT CONTRIBUTE TO SUSTAINABILITY IN WAYS NOT POSSIBLE BY ORGANIC POLYMERS. Silicones dramatically reduce energy consumption in areas like green tires (lower rolling resistance and better grip on the road), through architectural window glazing sealants (avoid heat loss and water ingress, and stable to UV irradiation), and silicones are essential components of electric vehicles, to which the whole world is moving. It would not currently be possible to manufacture a modern vehicle, either electric or internal combustion, without silicone polymers. There are many more examples where removal of silicones from commerce will be detrimental to the goals of improved sustainability.  An objective look at all the science around small cyclic silicones demonstrates their ability to migrate to/across air interfaces where effective environmental and microbial degradation processes return them to their natural starting materials: sand; water; and CO2. A declaration of POP is not only unwarranted, it contradicts the extensive available science. It would further hinder our ability to move towards a sustainable future.  Sincerely,  Michael A. Brook Distinguished University Professor Professor of Chemistry and Chemical Biology Faculty of Science Chair in Sustainable Silicone Polymers 2023 Winner of the Canadian Chemistry and Chemical Engineering Award for Green Chemistry |

|  |  |  |
| --- | --- | --- |
| **46**  **Date:**  2023/08/07 12:15 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Deutsche Bauchemie e.V.  **Org. country:**  Germany | **General Comments:**  The industry association Deutsche Bauchemie welcomes and supports the European Commission’s ambition to control the release of D4, D5 and D6 to the environment.  The European Commission intends to submit a proposal for a nomination of the cyclic siloxanes D4, D5 and D6 to Annex B of the United Nations Stockholm Convention on Persistent Organic Pollutants (POPs).  These cyclic siloxanes are essential building blocks for the production of silicone polymers. Sealants based on silicone polymers play a major role in the construction sector. Because of their durable, highly effective mechanical, optical and thermal properties they are widely used and difficult to substitute. As flexible connection joints between various materials in the building, they make an important contribution to the service life and quality of the entire building, but also ensure significant energy savings and thus support the goals set in the European Green Deal. It is therefore of upmost importance, that these silicone products remain available on the European single market.  Industrial downstream users (formulators) that provide silicone sealants, depend on the availability of high-quality silicone polymers in Europe as well as the legal authorisation to use those polymers in its products (mixtures).  For the construction chemicals sector, it remains unclear which consequences are to be expected, if the cyclic siloxanes D4, D5 and D6 are added to Annex B of the POP-Convention and whether there is a risk of a restriction in the availability or usage of silicone polymers as feedstock for silicone products. In our opinion, it must be ensured that D4, D5 and D6 continue to be available to manufacture silicone polymers in Europe under industrially controlled conditions and to use the resulting silicone polymers as starting materials for construction sealants. It is therefore essential, that a legal, technical, socio-economic and scientific assessment is in place, addressing any direct and indirect consequences that such a listing would have on silicone manufacturers and downstream users before submitting a proposal for nomination. |

|  |  |  |
| --- | --- | --- |
| **47**  **Date:**  2023/08/07 18:06 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Evonik Operations GmbH  **Org. country:**  Germany  **Attachment:** | **General Comments:**  Please find our comments under section IV. |

|  |  |  |
| --- | --- | --- |
| **48**  **Date:**  2023/08/08 10:23 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Attachment:**  <redacted>  **Privacy comment:**  individual company specific business confidential information | **General Comments:**  Confidential comments only; see Section V. |

|  |  |  |
| --- | --- | --- |
| **49** (50, 51 repeated comment submission)  **Date:**  2023/08/08 17:54 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Privacy comment:**  none | **General Comments:**  Our company is a downstream user of silicone polymers and silicone plasticizers. We are manufacturing (compounding) with silicone polymers and plasticizers several products for different applications in construction and in industry applications. We use only such raw materials when levels of D4, D5 and D6 are below 0,1%.. Silicone polymers and plasticizers may be produced by our suppliers based on cyclic dimethyl siloxanes or other precursors. However, our compounding process does not deal with levels of larger than 0,1% of the cyclic compounds of D4, D5 or D6. Subsequentially, our final products produced with such silicone polymers and plasticizers also do not contain higher levels of D4, D5 and D6 as the raw materials involved. The use of such silicone end-products is very diverse within construction applications and within applications in industry. Among such applications are: • Sealants for sanitary applications combining elastic properties with resistance to water and cleaning agents to provide long-term resistance better than other sealant technologies. • Sealants for glazing applications in window providing elastic properties with resistance towards UV- and weather exposure in combination with long-term adhesion properties, and also long-life stability in the range of several decades as window units itself. • Sealants for façade and flooring applications with high movement capability to compensate movements in the joint between façade elements and between façade other construction elements like doors, windows, pipe penetrations and other built-in-parts. • Silicone sealants are used by down-stream users, by professional applicators, semi-industrial processes and consumers. • Adhesives for industrial applications like in the appliance industry, such as the stove surfaces especially ceramic glass bonding and glass to metal frame bonding in doors. Sealants combine good adhesion and high elasticity with an almost permanent heat resistance of 250°C (and short-term above up to approx. 300°C). Life expectancy of such adhesives is in the same range as white goods avoiding replacing adhesive and unnecessary repair efforts. • Adhesives for the automotive industry to bond plastic, glass and metal elements. Automotives and its components are exposed to very low temperatures (e. g. -30°C) and to very high temperatures (e. g. +80°C) and temperature changes may occur suddenly and rapidly e. g. driving during weather changes in summer periods. Silicone products do stay quite stable in elasticity, in mechanical properties and adhesion properties within this temperature range in comparison to other polymeric technologies. • Potting materials for electronic parts e. g. used in automotive industry providing softness of an elastomer with the non-conductive properties required in electronic parts. • Silicone products can be produced transparent as well as in colored versions with a glossy and a matte surface providing the optical and esthetic appearance required in certain applications. We want to highlight with above examples that products made on silicone polymers and plasticizers are essential to many markets. Raw materials like silicone polymers and plasticizers are essential to manufacture / compound such products. It therefore must be ensured that D4, D5 and D6 can be used as building blocks in silicone polymer and plasticizer manufacturing at our suppliers with controlled levels on the final products that we use as starting raw materials in our compounding process. |

|  |  |  |
| --- | --- | --- |
| **52**  **Date:**  2023/08/09 04:26 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Cosmetic Industry Association  **Org. country:**  Japan | **General Comments:**  Japan Cosmetic Industry Association representing cosmetic industries of Japan, would like to submit the following comments on the possible nomination of cyclic siloxanes　(D4/D5/D6) to the lists of POPs under the Stockholm Convention.  Cyclic siloxanes (D4/D5/D6) have been discussed for impacts on human health and/or environment several decades from regulatory point of view. However, to date, there is no regulatory consensus around globe based on scientific evidence with respect to their mobility, ‘long-range’ transport, bioaccumulation or biological toxicity to humans.  D4, D5 and D6 are also intermediates used in the manufacture of silicone polymers. If they were to be nominated and listed as POPs, these cyclic siloxanes used in critical applications in various industries would no longer be able to be manufactured and used, and the impact on the industry and society would be enormous. In the cosmetics industry, both these cyclic siloxanes and silicone polymers are used in cosmetic products that provide smooth feeling benefits when rubbing their formulations and water/oil repellent effect for long lasting that are difficult to replace. We are very concerned about these negative impacts on cosmetics industry and loss of such benefits for consumers.  We think it would be practically impossible to exclude polymers from regulation once D4, D5 and D6 were regarded as POPs. If the European Commission were to submit a proposal to the POPRC to exclude polymer applications by ANNEX B, it would be almost impossible to control such a discussion within the POPRC.  As we mentioned above, Japan Cosmetic Industry Association is opposed to POPs nominations of D4, D5, and D6. We therefore request the European Commission to review the intent of the POPs nomination with careful consideration of its impact on industry and society. |

|  |  |  |
| --- | --- | --- |
| **53 (64 repeated comment submission)**  **Date:**  2023/08/09 04:46 | **Type:**  Individual  **Country:**  United States of America  **Attachment:**    **Privacy comment:**  No confidential information is included in my submission. | **General Comments:**  An attachment containing my detailed technical comments is included under Section IV. |

|  |  |  |
| --- | --- | --- |
| **54**  **Date:**  2023/08/08 17:16 | **Type:**  Individual  **Country:**  Canada  **Attachment:** | **General Comments:**  My comments are in the attached files |

|  |  |  |
| --- | --- | --- |
| **55**  **Date:**  2023/08/09 11:45 | **Type:**  Individual  **Country:**  Germany  **Attachment:** | **General Comments:**  Based on my background in toxicology, toxicokinetics, and human health hazard and risk assessment, my comments are restricted to chapter 3.4.2 and section 4. I have more than 40 years of experience in toxicology research and have been member of a number of expert panels addressing hazard and human health risks of chemicals and have published more then 400 articles in high impact peer-reviewed journals, including publications on the toxicology and modes of action of D4 and D5. |

|  |  |  |
| --- | --- | --- |
| **56**  **Date:**  2023/08/09 14:34 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  ChemSec  **Org. country:**  Sweden | **General Comments:**  Chemsec supports the nomination of D4, D5 and D6 to the Stockholm Convention on POPs. It is clear and thoroughly shown in the proposal that these substances do meet the screening criteria. However, we do not support the proposed AnnexB listing. We do not see any justification for such listing and we strongly recommend an AnnexA listing for these substances. |

|  |  |  |
| --- | --- | --- |
| **57**  **Date:**  2023/08/09 11:35 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  European Environmental Bureau (EEB)  **Org. country:**  Belgium | **General Comments:**  The European Environmental Bureau (EEB) supports the nomination of Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6) to the Stockholm Convention on Persistent Organic Pollutants due to their Persistent, Bioaccumulative and Toxic (PBT) and/or very Persistent, very Bioaccumulative (vPvB) properties.  These chemicals pose a Global risk to the environment and therefore should be eliminated globally by listing them in Annex A.  Listing in Annex B would create a loophole allowing further emissions. |

|  |  |  |
| --- | --- | --- |
| **58**  **Date:**  2023/08/09 12:43 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  BDSV e.V. (Federation of German Security and Defence Industries)  **Org. country:**  Germany | **General Comments:**  BDSV is the Federation of the German Security and Defence Industries and as such represents over 230 companies that produce security and/or defence equipment in Germany. BDSV welcomes the opportunity to give input regarding the ECHA proposal to include the substances D4, D5 and D6 in the Stockholm Convention as POP substances (in addition to REACH).  The siloxanes D4, D5 and D6 are essential intermediate substances in the industrial production of defence and security equipment parts. Parts made from silicon polymers are important and widely used components in various products in our sector, and are present for example in tanks, ammunition, submarines, sensor systems, weapon systems, helicopters and fighter aircraft.  Due to their high temperature resistance and adaptability to different shapes, silicones are for example used as sealants in many electronic equipment or doors and windows. Silicon based sealants and encapsulations protect the very sensitive electronic equipment in many defence products from outdoor influences like humidity, vibration, shock or dirt. BDSV wishes to highlight that defence products need to operate reliably in often very harsh environmental conditions and extreme temperature ranges. It is thus primordial that the silicone parts maintain their positive properties throughout those conditions and over the entire, very long lifespan of our products (up to multiple decades). It is therefore very difficult to find suitable substitutes for these silicone parts; and BDSV does not currently know any suitable alternatives.  In accordance with the opinion of the association Silicones Europe, BDSV members are not in favour of the ECHA proposal to include D4, D5 and D6 into the Stockholm convention. We see the severe risk of supply chain disruption in the EU for these substances if they are listed as POPs. Thus, while the current regulation of D4, D5 and D6 via REACH restrictions targeting mainly cosmetic applications seem to cause no risk for our industry, the additional regulation as POPs could cause very negative side effects for our industry regarding the reduced availability of silicone parts made in Europe. It is clear to us that dependencies from non-EU countries (like China) for supplies of these materials are no viable option for our strategic sector, and would go against political interests of the EU member states.  Accordingly, BDSV urges ECHA to not pursue the inclusion of D4, D5, D6 into the Stockholm convention at this stage, but to rather focus on the implementation of the already proposed REACH regulations of these substances and to decide on the necessity for further regulation in an impact assessment only once the REACH restrictions on D4, D5 and D6 have been into force for several years. It appears to us that, at that time in the future, it might become clear that there is no need or benefit in further regulating these substances beyond REACH.  BDSV stands ready for further discussions to fill-in more details. |

|  |  |  |
| --- | --- | --- |
| **59**  **Date:**  2023/08/09 15:57 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Attachment:**  <redacted>  **Privacy comment:**  Protection of our commercial interests | **General Comments:**  No comments |

|  |  |  |
| --- | --- | --- |
| **60 (98, 99, 109, 111 repeated submission)**  **Date:**  2023/08/09 02:15  2023/08/10 20:53 | **Type:**  Individual  **Country:**  Canada  **Attachment:**    **Privacy comment:**  n/a | **General Comments:**  Dear Sir/Madam,  Please find attached my comments to the scientific dossier.  Best regards, Frank Gobas Professor at Simon Fraser University in Canada gobas@sfu.ca |

|  |  |  |
| --- | --- | --- |
| **61**  **Date:**  2023/08/08 16:27 | **Type:**  Individual  **Country:**  Canada  **Attachment:** | **General Comments:**  This is a joint submission by Michael McLachlan of Stockholm University in Sweden and Frank Wania of the University of Toronto Scarborough in Canada.  Please note that we are submitting the comments in two different formats: 1. Using the Excel sheet with the recommended format for providing comments 2. Using a PDF document, which contains the same information, but is structured more cohesively, has better formatting and can properly display figures and tables. |

|  |  |  |
| --- | --- | --- |
| **62**  **Date:**  2023/08/09 11:15 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany | **General Comments:**  Sto SE & Co. KGaA is a manufacturer of construction products, e. g. coatings, mortars, plasters, adhesives, for various applications in the construction sector. Silicone polymers are used for the formulation of a considerable number of such products. The chemical and physical properties of silicon polymers contribute to material properties like low water absorption, weatherability, and durability. These properties are very important for construction products in order to support the sustainable use of buildings by protection against water ingress, freeze and thaw stress, and weathering, thus extending the service life of construction products and buildings. PFAS based polymers could serve as substitutes for silicone polymers at least for part of these applications, however, due to the well known environmental profile of PFAS, this is not considered as an option. Thus suitable substitutes for silicone polymers do not seem to be available. We welcome the ambition to control the release of D4, D5, D6 to the environment. As a manufacturer of construction products we do not use these substances as such, however, make use of polymers based on these substances in order to achieve beneficial properties of construction products as described above. The consequences of D4, D5, D6 to be aded to Annex B of the POP-Convention on the use of these substances as intermediates seem to be not clear. To our opinion it must be ensured that industrial use of D4, D5, D6 as monomers for the production of silicone polymers, and the use of such polymers, will remain possible in future. If it would be considered necessary to add D4, D5, D6 on Annex B of the POP-Convention, appropriate definition of "acceptable purposes" and/or "specific exemptions" are vital. Industrial use as intermediate must be exempted, as well as the use of silicone polymers, provided that release of D4, D5, D6 to the enviroment is minimized to acceptable limits. The current proposal for an amendment of REACH Annex XVII Restriction Nr. 70 contains detailed regulations on such exemptions. A possible entry on D4, D5, D6 in the POP-Convention would have to be shaped in a similar way. |

|  |  |  |
| --- | --- | --- |
| **63**  **Date:**  2023/08/09 17:20 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  National NGO  **Org. name:**  Arnika  **Org. country:**  Czech Republic | **General Comments:**  Arnika applaudes ECHA for nominating siloxanes D4, D5 and D6 as they meet the criteria for inclusion under the Stockholm Convention. The proposal has one major problem, which is the suggestion to list these substances under Annex B of the Convention. This would mean a phase down of the use rather than global elimination. Majority of substances are listed under Annex A meaning the goal is full restriction aiming at global elimination. As of this moment, the only two POPs listed in Annex B are PFOS and DDT, and while they were listed in 2009 and 2001 respectively, they are still in use in countries around the world, therefore contributing to toxic burden of the entire human population. There is no justification in the proposal to list siloxanes in Annex B but they shall be proposed to list under Annex A. |

|  |  |  |
| --- | --- | --- |
| **65**  **Date:**  2023/08/09 18:20 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  CTPA (Cosmetic, Toiletry and Perfumery Association)  **Org. country:**  United Kingdom | **General Comments:**  CTPA Response to the Consultation by the European Commission on a nomination of D4, D5, and D6 for inclusion in the Stockholm Convention as POPs substances 10 August 2023  Representing all types of companies involved in making, supplying and selling cosmetics and personal care products, the Cosmetic, Toiletry and Perfumery Association Limited (CTPA) acts as the voice of the UK industry. CTPA represents, at any given time, around 200 member companies of diverse sizes and types, from SMEs through to multinationals. This collectively represents between 85-90% of a UK market valued at £8.9 billion in 2022 (at retail sales price).  This industry produces products that are absolutely critical to everyday life, including sun protection, oral care, including toothpaste, soap, antiperspirants and deodorants, shampoo, hand sanitisers and skin care as well as colour cosmetics, hair styling and grooming products for both women and men. Research conducted in 2022 for the CTPA by Opinium\* showed that 85% of UK adults class cosmetics and personal care products as essential to their lives; the figure is even higher among women, at 94%.  The UK is a Party to the Stockholm Convention and it has a National Implementation Plan to manage Persistent Organic Pollutants (POPS) in the UK in accordance with the obligations under the Convention. Therefore, any chemicals listed under the Stockholm Convention will have a direct impact on the UK and other international markets.  On the points of principle that the science is not universally aligned on the classification of D4, D5 and D6 as POPs and the precedent being set on regulating intermediates under the Stockholm Convention, CTPA has concerns over the proposed EU Commission nomination of D4, D5 and D6 to the POP list under the Stockholm Convention.  The Commission considers that D4, D5 and D6 demonstrate persistence and long-range transport, and that measures taken nationally or regionally are not sufficient to safeguard a high level of protection of the environment and human health. Therefore wider international action is necessary.  While CTPA is fully committed to reducing the environmental impact of cosmetics and personal care products and their ingredients wherever possible, and is supporting its members in their sustainability activities, any action taken must be based on sound science and robust evidence of an environmental risk.  However, for cyclic siloxanes there is no consensus across the international scientific community, and other global parties, on whether they meet the criteria to be classified as POPs, especially regarding long range transport and deposition. This is exemplified by the different scientific conclusions reached in different global jurisdictions, resulting in no action being taken in some areas and strict restrictions in others. For example, severe restrictions on downstream uses in the EU for D4, D5 and D6, yet minor controls on D4 and no controls on D5 and D6 in both Canada and Australia. Scientific assessment and any possible risk management options are currently under consideration in the UK, and the UK Government has not yet made a policy decision on these substances. Until greater consensus is achieved, it would be premature to nominate these substances for listing under the Stockholm Convention. Such a nomination would also significantly undermine the important scientific- and risk-based regulatory assessments that have been undertaken around the world that continue to support the conclusion that D4, D5 and D6 do not pose a significant environmental risk.  D4, D5 and D6 are critical monomers for the production of a wide range of silicone polymers. Levels of residual monomer vary and can be lowered as much as is technically feasible, but is not possible to guarantee complete absence.  For the cosmetics industry, silicone monomers are important building blocks for a variety of cosmetic ingredients which are essential for the performance of products; for example, due to their hydrophobicity, softness and fast-drying properties. These ingredients support consumer access to safe products that meet their expectations of quality and performance.  Silicone polymers are therefore directly under threat if D4, D5 and D6 are listed as POPs under the Stockholm Convention, which will in turn also have a detrimental impact on cosmetics manufacturers in GB. For example, a siloxane POP listing would likely create significant friction with respect to trade flows of siloxane monomers and siloxane-containing silicone polymers, if the monomer content exceeds threshold levels for traces, for exports from a Party like the EU to a non-EU country, such as Great Britain.  CTPA would like to express a serious concern on the impact of a listing on the availability of silicone polymers in its members’ value chains. There are also implications for trade flows of wastes containing siloxanes for disposal or recycling, particularly if the EU succeeds in its parallel proposal to amend the Basel Convention to classify any waste containing a POP at levels that exceed a “low POP threshold” as a hazardous waste.  The EU has already implemented severe restrictions on the use of D4, D5 and D6 for downstream users including the cosmetics industry. Considering that other jurisdictions have evaluated these substances and implemented measures, or not, which are considered appropriate based on the scientific conclusions, a POP nomination would be disproportionate, and either challenge or pre-empt the decisions of other jurisdictions.  If silicone monomers are nominated for a POP listing, this would be the first time that the Stockholm Convention has been proposed as a tool to regulate intermediates. A listing for monomers in the Stockholm Convention will therefore generate much legal uncertainty, which could lead to enforcement challenges and leave the measure open to lengthy legal challenge.  On the points of principle that the science is not universally aligned on the classification of D4, D5 and D6 as POPs and the precedent being set on regulating intermediates under the Stockholm Convention, CTPA does not support the EU Commission nomination of D4, D5 and D6 to the POP list under the Stockholm Convention.   \*Opinium polled 2,000 UK adults between 25 February and 1 March 2022. See more information about this research in CTPA’s Annual Report 2021, ‘More Than a Feeling’. |

|  |  |  |
| --- | --- | --- |
| **66**  **Date:**  2023/08/09 19:28 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  International Pollutants Elimination Network (IPEN)  **Org. country:**  Sweden  **Attachment:** | **General Comments:**  The proposal comprehensively shows that D4, D5 and D6 meet the criteria in Annex D of the Stockholm Convention. However, the suggestion for a nomination with the intention of listing D4, D5 and D6 in Annex B of the Stockholm Convention is not justified and should either be changed to Annex A, and possibly also Annex C, or any suggestion of Annex be deleted not to preempt the thorough evaluation of the scientific expert committee under the Convention, the POPs Review Committee.  IPEN strongly supports a nomination for listing these in Annex A and possibly also Annex C of the Convention. Detailed comments have been provided as an attachment under Section IV. |

|  |  |  |
| --- | --- | --- |
| **67**  **Date:**  2023/08/09 22:10 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  <redacted>  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  Disclosing the uses of D4, D5 and D6 in the biopharmaceutical industry might affect the intellectual property and commercial interests of our members who submitted this information in confidence. | **General Comments:**  The biopharmaceutical industry has several uses of D4, D5 and D6 which have been submitted in a more detailed document attached to this submission. |

|  |  |  |
| --- | --- | --- |
| **68**  **Date:**  2023/08/10 08:33 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  <redacted>  **Org. country:**  China  **Attachment:** | **General Comments:**  General comment  The China Association of Fluorine and Silicone Industry welcomes the opportunity to provide comments on the technical dossier prepared by ECHA. Under REACH, D4, D5 and D6 are restricted for consumer and professional uses, we believe current restrictions under REACH is sufficient, the effect of such restrictions needs to be verified before moving towards any global action. ECHA’s proposal to nominateD4, D5 and D6 as new POPs is considered as an improportional and will have significant impact to European social economy and potentially harm the interest of European consumers, it will not only weaken the innovation and competitiveness of silicone industry but ultimately impact other innovative industries that rely on the silicone materials.  As an overall comment, CAFSI experts have identified that the dossier lacks a comprehensive review of all the available and especially peer-reviewed published data for D4, D5 and D6. We noticed that there are numerous publications have not been considered as evidences, therefore conclusions are drawn without taking those available data sets into consideration. Introduction The dossier states: “They are manufactured and used in a variety of sectors such as the construction (sealants, paints and coatings), automotive (parts and lubricants), electronics, pulp and paper, oil and gas, medical and aerospace/defence sectors.”  The text in section 1.1 above implies direct use of the monomers D4, D5 and D6 in these applications, however in most cases it is silicone polymers made from monomers D4, D5 and D6 that are used in the applications listed.  Technical Portion: (Chemical Identity and Information on D4, D5, D6 and assessment whether they fulfil the Annex D screening criteria for Persistence, Bioaccumulation and the Potential for Long-Range Transport (LRT))  a. In the dossier of Draft Annex D proposal, it states that ECHA relied upon authoritative assessments, peer review and grey literature, there are more than 50 recent peer-reviewed literature publications and authoritative assessments still missing. b. Some of the conclusions drawn by dossier does not demonstrate an objective assessment, they are based on selected data or selective text from study reports and publications or may not have a sound scientific basis. For example, the dossier states: “D4 and D5 have a high tendency to adsorb to sediments and particles which hinders hydrolysis.” Silicones Europe’s comment: Hydrolysis half-life is an intrinsic property of the substance at a given pH and temperature. Sorption may influence the contribution of hydrolysis to the fate in a specific environment, but sorption does not directly influence hydrolysis. The extent to which sorption attenuates hydrolysis (or other processes such as volatilization) under specific environ-mental conditions can and c. We notice the obvious bias existence, e.g. the dossier provides a highly critical review of the industry studies or studies that do not support meeting the Annex D criteria. Meanwhile, it justifies those non-industry studies with the same level of uncertainties, they should be taken seriously, and the precautionary principle should be applied. The dossier states in paragraph 32 that “It is apparent that different conclusions can be drawn from some studies depending on i) The authoritative assessment by Australia authority pointed out “Substances with a log KOA less than 6 are not expected to bioaccumulate in air-breathing animals (Kelly, et al., 2007). The measured log KOA values for D4, D5 and D6 are all less than 6 which indicates that they should not biomagnify in air-breathing animals. This expectation has been confirmed experimentally for D5 where respiratory elimination of this chemical in rats and humans has been demonstrated (Gobas, et al., 2015).” ii) An independent study (Xu, etal., 2012) indicates These methyl siloxanes were eliminated from human plasma with half-lives ranging from 2.34 to 9.64 days, that demonstrate low tendency of accumulation. d. The dossier disregards and does not acknowledge the conclusions of scientific experts who have already reviewed the monitoring data available on cVMS in remote regions. The peer-reviewed and publicly available literature contains reviews indicating that the presence of these materials in remote regions is more likely attributed to local sources rather than long-range environmental transport e. The dossier on several occasions distorts the data by making broad conclusions with no basis for the conclusions. i) For example, the dossier states: “Considering the high global volumes of these sub-stances even a low percentage of deposition and transfer to a receiving matrix (water (including sediment) or soil) is of potential concern for remote areas” – Yet, no calculation was done to verify this. ii) For example, the dossier indicates multiple modes of LRT contribute to the presence of cVMS in remote polar regions. Without calculating the potential contribution of those modes of LRT to assess, it is difficult to assess whether they could lead to detectable concentrations.  Technical Portion (Adverse Effects) 　  a. According to criteria detailed in Annex D, evidence of adverse effect to human health or the environment, or data that indicate the potential for adverse effects to human health and the environment needs to be provided, any nomination of new POPs should carefully exam all available evidences and review if evidence is relevant to human. Here we support our sister organization Silicone Europe’s opinion and does not believe this has been demonstrated, i) The dossier relies on the presence of any toxicity seen in laboratory studies including when dosing levels are much higher than solubility limits of cVMS and significantly higher than any concentrations found in the remote environment to allude cVMS cause adverse effects ii) In addition, Assessment of the human health and environmental impacts of chemicals, including cyclic siloxanes, as part of the Inventory Multitiered Assessment and Prioritisation (IMAP) framework conducted by Australian authority, the health assessment for D4 and D5 completed with conclusion: For D5, there are no critical health effects for D5. The dossier has mischaracterized the mode of action of D4 reproductive toxicity and uterine effects as being relevant to humans, when it is well established that rodents and human differ significantly in regulation of this pathway. b. The dossier does not follow the requirements of the text of Annex D that indicates where possible a comparison of the toxicity or ecotoxicity data with detected level of a chemical should be done. c. The dossier carries out no comparison of the measured data in remote regions to the effect levels. Such a comparison would demonstrate there is no potential for adverse effects in remote regions. |

|  |  |  |
| --- | --- | --- |
| **69**  **Date:**  2023/08/10 08:34 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Korea Cosmetic Association  **Org. country:**  Korea, Republic of | **General Comments:**  ﻿Submission of KCA's Opinion on ECHA's Proposal to Designate D4, D5, and D6 as Persistent Organic Pollutants (POPs) under the Stockholm Convention  Korea Cosmetic Association, which represents Korean Cosmetic Industry, would like to submit the following opposing opinion regarding the possible nomination of D4, D5, and D6 to the lists of POPs under the Stockholm Convention.  D4, D5, and D6 are being utilized in various types of cosmetics, including skincare, makeup, and hair care products. These substances provide a distinct silky smoothness while reducing friction in hair care products, enhancing hair texture. In makeup products, they are employed for their adhesive properties and film-forming purposes.  As there are no practical alternatives that can maintain these characteristics, if D4, D5, and D6 are designated on the Stockholm Convention's POP list, the cosmetics industry would face significant repercussions due to the inability to retain these attributes.  D4, D5, and D6 can unintentionally persist not only from direct usage but also from other polymer sources, making a complete ban or comprehensive emission control practically unfeasible.  Given the lack of regulatory and scientific consensus on whether these substances are bioaccumulative or inherently toxic, if D4, D5, and D6 were added to the 'Persistent Organic Pollutants (POPs)' list, it would pose significant challenges to the industry.  Therefore, until a thorough evaluation is conducted from legal, technical, socio-economic, and scientific perspectives, we kindly request the withdrawal of this proposal. |

|  |  |  |
| --- | --- | --- |
| **70**  **Date:**  2023/08/10 09:47 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Business Council in Europe (JBCE)  **Org. country:**  Belgium  **Attachment:** | **General Comments:**  JBCE understands that the draft scientific dossier for D4, D5 and D6 is in line with the target of having “a zero-pollution ambition for a toxic-free environment” which was proposed in the “Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment- (CSS)”. However, despite agreeing with and supporting its concept and purpose to protect human health and the environment, we would like to point out that the currently proposed restriction raises various issues which need to be addressed in terms of scientific reasoning and socio-economic impact, as highlighted by various companies across different impacted sectors represented by JBCE. Our main points of concern are listed below.  • Silicone polymers made from raw materials including D4, D5 and/or D6 with special properties such as excellent heat resistance, low thermal conductivity, thermal stability, electrical insulation, gas permeability, non-stickiness and oil resistance are widely used in a variety of industries all over the world. The products which use silicon polymers (i.e. EV batteries, coatings, lubricants, cables, solar cell connectors, sensors, PV panels, LED lighting, medical devices, food contact materials as well as analytical and measurement equipment) are necessary applications to reach the goals of the European Green Deal, to protect human health and foster innovation, they therefore play a very important role in society.  • JBCE is seriously concerned that POPs nomination of D4, D5 and D6 will lead to strict restrictions on the production, use, and trade of silicone polymers. In particular, in electrical and electronic equipment (EEE), the components and the parts using silicone polymers are the key technologies enabling the special performance and the products’ reliability. The manufacturers of EEE would have to find alternative substances if silicone polymers were to become subject to restrictions under Annex B to the convention. However, finding alternative substances with the same special properties as silicone polymers would be extremely difficult. Even if a potential alternative substance for silicone polymers could be identified, it is not given that it could become a real and viable alternative in final products. It would still need to be proven whether the final product shows the same level of performance after the design change. It needs to be considered that many industrial sectors of course must comply with chemical and environmental regulations, but in addition also with sector-specific stringent product-related regulations as well as performance and safety standards.  • JBCE urges ECHA to carefully consider the risk assessment about the release of D4, D5 and D6 to environmental media from all the applications using silicone polymers and the socio-economic analysis if silicone polymers become subject to restrictions under Annex B to the convention. Furthermore, we believe that setting specific derogations for the applications using silicone polymers similar to the ones in the Stockholm Convention decision for UV-328 should be considered. |

|  |  |  |
| --- | --- | --- |
| **71**  **Date:**  2023/08/10 11:21 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Association of Chemical Industry of the Czech Republic  **Org. country:**  Czech Republic | **General Comments:**  Association of Chemical Industry of the Czech Republic represents also the interests of its member companies-downstream users of silicones. Silicones’ unique performances and properties make them the material of choice for essential applications in many sectors, such as energy sector, healthcare, construction,electronics sector, … Silicones are essential materials for implementation of the European Green Deal and creation of the strategic autonomy. In our opinion, a POP listing of D4 D5 D6 under the Stockholm Convention is not an appropriate tool to regulate these substances and risks disrupting the silicones value chain in Europe. We believe that the recent European Commission’s proposal to nominate D4, D5 and D6 under Annex B to the Stockholm Convention on POPs does not take full account of the whole body of scientific evidence and should have recognised already applicable or on-going regulatory activities.  When it comes to the implementation of the Stockholm Convention in the EU, the potential inclusion of D4/5/6 in the EU POPs regulation would affect the trade, production, and accessibility of silicones across the globe and hamper the ability of EU downstream users to access silicones. Ultimately, this would hamper value chains established in Europe, in favour of other regions where the access is secured in a timely and affordable manner. Before any proposal is presented to the Council of the EU, the European Commission shall:   Consider all the available scientific information to understand whether D4/D5/D6 meet the criteria of Persistent Organic Pollutants under the Stockholm Convention.   Address the technical, legal, socio-economic aspects of a listing of D4/D5/D6 under the Stockholm Conventions as well as any direct and indirect consequences that such a listing would have on silicone manufactures and downstream users.  We call on the European Commission to recall their proposal to nominate D4/5/6 as POPs under the Stockholm Convention, before a thoughtful legal, technical, socio-economic and scientific assessment is in place. It is also necessary to take into account that the EU27 shares of global chemicals market drops substantially (from 27% in 2001 to 15% in 2021- source Cefic´Facts&Figures 2023). |

|  |  |  |
| --- | --- | --- |
| **72**  **Date:**  2023/08/10 11:31 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  DuPont de Nemours Inc.  **Org. country:**  United States of America  **Attachment:**  <redacted>  **Privacy comment:**  DuPont de Nemours Inc submission document does contain details on a particular application which are considered as proprietary for the company. Releasing this information publicly could be detrimental to DuPont de Nemours Inc business. DuPont de Nemours Inc would like this information to be maintained confidential in this view. Remark we feel we may encounter some technical issue in the upload of this document. Here is what we see at screen C\fakepath\DuPont de Nemours Inc.pdf. The document does not show up as being uploaded. If indeed the document named " DuPont de Nemours Inc " is not uploaded, please reach out the contact mentioned above, we would send the document via E-mail. thank you for your understanding. | **General Comments:**  DuPont de Nemours, Inc. is a downstream user of siloxane polymers and is commenting the proposed nomination as a downstream user. Please find DuPont de Nemours, Inc.’s comments in the attached document |

|  |  |  |
| --- | --- | --- |
| **73**  **Date:**  2023/08/10 12:32 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Silicones Europe, a sector group of Cefic  **Org. country:**  Belgium  **Attachment:**    <redacted>  **Privacy comment:**  The sector group member has provided the attached study reports for submission to ECHA as confidential (to protect their commercial interests and intellectual property) in support of the industries comments on the D4, D5, D6 Technical Dossier. Additional reports will be submitted separately due to file size limits. | **General Comments:**  Silicones Europe and the Global Silicones Council have prepared detailed scientific comments for the public consultation on the “Draft proposal to list D4, D5 and D6 in Annex B to the Stockholm Convention on Persistent Organic Pollutants”. These comments are provided in the requested format and have been uploaded. We have also shared several unpublished studies that are industry owned and requested by ECHA. The silicones industry welcomes the opportunity to provide comments on the technical dossier prepared by ECHA. As an overall comment, our experts have identified that the dossier lacks a comprehensive review of all available data and especially peer-reviewed published data for D4, D5 and D6 (hereafter referred to as cyclic volatile methylsiloxanes (cVMS)). Based on the cited studies, numerous publications have not been considered. In addition, even though it states often in the dossier that ECHA relied on references in the REACH registration dossiers, our experts identified instances in which ECHA seems to misstate what is actually in the REACH registration dossiers including indicating a study doesn’t exist when it is actually in the dossier. Therefore, the dossier makes conclusions that do not consider all relevant and available data sets. Hereafter, the silicones industry has outlined further high-level concerns section by section (document attached in section IV), all which are elaborated further in our input to the public consultation. |

|  |  |  |
| --- | --- | --- |
| **74**  **Date:**  2023/08/10 13:35 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  United Kingdom  **Attachment:**  <redacted>  **Privacy comment:**  Protection of commercial interests, including intellectual property, would be undermined. | **General Comments:**  I understand |

|  |  |  |
| --- | --- | --- |
| **75**  **Date:**  2023/08/10 15:14 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Dow  **Org. country:**  United States of America  **Attachment:**    <redacted>  **Privacy comment:**  Protection of Dow's commercial interests, including intellectual property, would be undermined. | **General Comments:**  see attachment. |

|  |  |  |
| --- | --- | --- |
| **76, 78-89, 91-94, 96, 100-108**  **Date:**  2023/08/10 17:22-19:39 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Silicones Europe, a sector group of Cefic  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  The sector group members have provided the attached study reports for submission to ECHA as confidential (to protect their commercial interests and intellectual property) in support of the industries comments on the D4, D5, D6 Technical Dossier. Additional reports will be submitted separately due to file size limits. | **General Comments:**  Comments and non-confidential attachments (including the spreadsheet) provided in an earlier submission. |

|  |  |  |
| --- | --- | --- |
| **77**  **Date:**  2023/08/10 17:25 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Alliance Pharmaceutical Ltd  **Org. country:**  United Kingdom  **Attachment:** | **General Comments:**  Regarding technical content of proposal please find attached the template provided.  Regarding "alternatives, costs and benefits related to the use of the substance and well justified requests for exemptions if no alternatives are available" see below.  Use: Medical devices used for scar treatment and stoma care  The substance is essential for the function of the finished product. D5 displays a series of physicochemical properties that make it an essential component of the medical device. Volatility - The volatility of D5 ensures the product dries quickly ensuring that an accurate silicone layer is formed over the scar. Alternatives assessed do not meet the safety profile of D5 as the flashpoint is significantly lower or the drying time is unacceptably long – leading to risk of product being wiped from area through clothing etc . Solubility of silicone polymer in D5 – To allow optimal performance of the product a solution of the silicone polymer needs to be used. D5 is an excellent solvent for the silicone polymer. Low flammability – The product is used in a domestic environment where there it is not possible to prevent sources of ignition. D5 is one of the few solvents that offers the volatility required for efficacious application of the silicone polymer without resulting in an elevated risk of ignition.  Any alternative would need to be assessed to ensure that: - The product is at least as efficacious as the current formulation using D5 - The safety profile is maintained - The formulation is stable and suitable for commercial manufacture There is no available suitable alternative for D5 for use in Scar Treatments that Alliance Pharmaceuticals is aware of. All alternatives assessed to date remain unsuitable due to low flashpoints or increased drying time.  No alternative has been identified for use in a scar gel treatment by Alliance Pharmaceuticals. The drying time, skin feel, viscosity, safety profile and physical characteristics of D5 are not matched by any product assessed to date. The volatility of D5 makes it a particularly suitable ingredient. When correctly applied, the gel dries in around 5 minutes. The remaining components combine to form a silicone elastomer that binds to the stratum corneum through a variety of physicochemical and electrostatic effects. The resultant film is relatively strong, smooth and cosmetically pleasant, with properties of gas permeability and water impermeability which are necessary for normal scar resolution. Increasing the concentrations of the non-D5 components has two potential undesirable effects: firstly, the drying time is greatly increased, making it less convenient for the patient; secondly, although the durability of the elastomer is increased, it will bind less strongly to the skin, which will reduce the effectiveness of the product .  International guidelines for the prevention and treatment of hypertrophic scars and keloids recommend the use of silicone gels as first-line or adjuvant therapy at various stages of the algorithm. Other therapies are available, such as ablative/non-ablative lasers, surgery, corticosteroids, radio/cryotherapy (for keloids) and certain cytotoxic compounds – again either alone or in combination. However, many or all of these are either less available and/or more expensive, less convenient and most pose additional risks to the patient. The loss of silicones as a means of treating and preventing excessive scarring would therefore present significant socio-economic disadvantages. |

|  |  |  |
| --- | --- | --- |
| **90**  **Date:**  2023/08/10 18:15 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Personal Care Products Council  **Org. country:**  United States of America  **Attachment:** | **General Comments:**  The Personal Care Products Council1 appreciates the opportunity to provide this response to ECHA’s consultation on the draft proposal to list Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6) to the Stockholm Convention as Persistent Organic Pollutants (POPs). Please see the attached letter. |

|  |  |  |
| --- | --- | --- |
| **95**  **Date:**  2023/08/10 18:23 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Cosmetics Europe  **Org. country:**  Belgium | **General Comments:**  The cyclic siloxanes octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dodecamethylcyclohexasiloxane (D6) are essential building blocks used as intermediate substances in the production of silicone polymers or as basic raw materials in the production of silicone rubbers, gels, and resins. Direct (non-intermediate) uses of these substances account for less than 2% of usage globally, whilst 98% is used for polymer production (intermediate use).  The European Commission has recently presented its intention to submit a proposal for a nomination of D4, D5, and D6 to Annex B to the United Nations Stockholm Convention on Persistent Organic Pollutants (POPs) whose objective is “reducing and ultimately eliminating the production and/or use of these chemicals”.  Cosmetics Europe is highly worried by this proposal and its likely negative impact on the availability of important key silicone polymers for use in cosmetic formulations, but also going far beyond the cosmetic sector to all areas of industrial use and everyday applications of these materials. Cosmetics Europe believes that a nomination of these substances as POP is unlikely to achieve the desired outcome nor is such a proposal based on a generally accepted scientific basis.  1) It is our understanding that the aim of the proposal is to extend the REACH restrictions that are currently under development for these substances beyond the EU and eliminate their direct (non-intermediate) use, while the use of the substances as intermediates for the manufacturing of polymers is not the target. This would necessitate a comparatively complex restriction entry on Annex B, which has never before attempted under the Stockholm convention and for which this system is not designed. Indeed, past experience shows clearly that POP listing resulted in undifferentiated elimination of the concerned chemicals. In practice, for pivotal silicone polymer use to continue, exemptions will be needed for over 95% of global D4, D5 and D6 production and would require several hundred thousand derogations in our estimation.  Cosmetics Europe is therefore of the opinion that a nomination as POP under Stockholm convention is not the appropriate tool to achieve the desired purpose of a “globalisation” of the restriction, but carries the very high risk of leading to a global ban of any use, production and trade of these substances with the loss of all polymers that are manufactured from these intermediates and which are important to lots of sectors and applications including the cosmetic industry.  2) Cosmetics Europe does not believe that D4, D5 and D6 fit the scientific criteria to be listed under the Stockholm Convention as POPs. The scientific discussion on the long-range transport and back deposition in remote polar regions is ongoing. Industry is contributing by conducting an extensive monitoring project in Antarctica with initial results due in Q3 2024. The study will be supervised by an independent panel to which Member States are invited to nominate scientific experts. A second study, supported in part by but independent from industry, is being conducted by the Norwegian Air Institute (NILU) in the Arctic with results expected in Q4 2023.  In conclusion, Cosmetics Europe believes that a nomination of D4, D5 and D6 as POPs is premature at best and the process should be put on hold to thoroughly assess the scientific, procedural, legal and socio-economic aspects and risks of a listing of these substances as POPs under the Stockholm Convention. At the same time, potential alternative and less risky routes to achieve the desired outcome should be explored. |

|  |  |  |
| --- | --- | --- |
| **97**  **Date:**  2023/08/10 18:35 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  National Association of Manufacturers  **Org. country:**  United States of America  **Attachment:** | **General Comments:**  Aug. 10, 2023  European Chemicals Agency Telakkakatu 6, P.O. Box 400 FI-00121 Helsinki Finland  Re: European Chemicals Agency POPs Consultation for Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); and dodecamethylcyclohexasiloxane (D6)  Dear Sir/Madam:  On behalf of manufacturers in the U.S., the National Association of Manufacturers appreciates this opportunity to provide input on the European Chemicals Agency Persistent Organic Pollutants (POPs) Consultation for Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); and dodecamethylcyclohexasiloxane (D6).  The NAM is the largest manufacturing association in the U.S., representing nearly 14,000 manufacturers small and large in every industrial sector and in all 50 states. Manufacturing employs nearly 13 million people across the country and drives innovation more than any other sector, contributing 55% of all private sector research and development in the U.S. In total, manufacturing contributed more than $2.9 trillion to the U.S. economy in the first quarter of 2023, an all-time high.  The NAM recognizes and appreciates the European Union’s commitment to environmental protection and the responsible use of chemicals. As always, manufacturers welcome the opportunity to engage directly with the EU to address specific concerns on regulatory matters as we seek to ensure sustainable and innovative supply chains for our industry. Manufacturers are committed to protecting worker and consumer safety, public health and our environment, and our industry strongly supports regulatory policies designed to support economic growth and adhere to sound principles of science, risk assessment and cost-benefit analysis. To that end, manufacturers have championed environmental stewardship at every turn, and our members have invested heavily in new processes and technologies that have made manufacturing in the U.S. cleaner and more sustainable than ever.  D4, D5 and D6 are essential building blocks in the production of silicone polymers used in diverse supply chains, including but not limited to medical devices, the automotive industry, semiconductors and consumer products. Restricting access to these polymers would harm manufacturing resiliency. Accordingly, manufacturers urge the EU to consider the impact on consumers and industries that use these chemicals in their production processes as it considers this topic.  The NAM welcomes this opportunity to provide feedback on this matter, and we look forward to continued engagement with the EU as the process continues.  Sincerely, Ken Monahan |

|  |  |  |
| --- | --- | --- |
| **110**  **Date:**  2023/08/10 20:29 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  BRAZILIAN CHEMICAL INDUSTRY ASSOCIATION  **Org. country:**  Brazil  **Attachment:** | **General Comments:**  Our comments are described at the annex (ABIQUIM Letter - Potential POPs Nomination-100823) |

|  |  |  |
| --- | --- | --- |
| **112**  **Date:**  2023/08/10 22:00 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  U.S. Chamber of Commerce  **Org. country:**  United States of America  **Attachment:**    **Privacy comment:**  We have no confidential comments or materials, only our public comments to this consultation. | **General Comments:**  Thank you for the opportunity to comment, please find the attached submission from the U.S. Chamber of Commerce, we appreciate your consideration. |

|  |  |  |
| --- | --- | --- |
| **113**  **Date:**  2023/08/10 23:40 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  The Polish Union of the Cosmetics Industry  **Org. country:**  Poland | **General Comments:**  - The Polish Union of the Cosmetics Industry represents and supports the strategic goals of entrepreneurs exclusively in the cosmetics industry in Poland. The Union brings together over 260 companies, including cosmetics producers and distributors, as well as their branch partners for e.g. suppliers of raw materials.  - Silicone components are often used in the manufacture of a polymer and key ingredients in many categories of cosmetic products, such as make-up products, hair care products or facial products. In certain products silicones are present in concentrations up to 100%, so they are the only component of the product. Examples of product groups containing more than 70% of siloxanes are make-up products (primers, bases applied under make-up), make-up removers, hair serums and oils. Make-up foundations are important and specific product category where silicones are particularly difficult to replace. Moreover, silicones are used as emollient ingredients (skin conditioning), hair conditioning, cleaning and as solvents. It should be noted that silicones are characterized by specific polarity, which affects their unique physico-chemical properties. Silicones have a unique effect on the sensory properties of the product − due to their volatility they do not cause the "greasiness" effect and do not create an oily, sticky layer on the surface of the skin or hair. They give a "silky touch" effect on the skin / hair. The described in-use properties of products due to the silicones use are particularly appreciated and highly desired by the consumers and essential for certain product types. The described in-use properties of products due to the silicones use are particularly appreciated and highly desired by the consumers and essential for certain product types. There is currently no universal and direct one-for-one available substitutes for most silicones. There are no substitutes available for many silicones used by the cosmetics industry. Replacing silicones/polymers in different personal care product types needs to be addressed on a case-by-case basis and requires a new formulation approach with the creation of a new products architecture in order to achieve a products which matches the desired performance characteristics and sensory benefits. The reformulation process should not limit the consumers’ choice and acceptance of products, especially make-up and hair products, as those categories are expected to the most challenging in reformulation process. This is because siloxanes give products of categories mentioned - unique and specific application properties. Silicones remain on the skin and hair surface after application. They form a film, a thin layer, giving unique experience of smoothness and ease of speading. On hair silicones gives set of unique properties: act anti-static (i.e. prevent static), make combing easier or and gives shine including damaged or coloured hair. On the face silicones deliver complexion smoothing, non-greasiness (important for oily and acne skin) and ease of application, the latter highly important in make-up products. The layer formed by silicones is, however, permeable to other chemicals, including water and gas molecules.  - The Polish Union of the Cosmetics Industry strongly believes that the recent European Commission’s proposal to nominate D4, D5 and D6 under Annex B to the Stockholm Convention on Persistent Organic Pollutants does not take full account of the whole body of scientific evidence, should have recognised already applicable or on-going regulatory activities, and puts at risk numerous beneficial uses including in the cosmetics sector.  - Silicone polymers rely on D4, D5 and D6 as building blocks (monomers) for their manufacturing. Silicone materials are widely used and difficult to substitute because of their durable, safe and highly effective mechanical, optical and thermal properties.  - Silicones are essential to build a green value chain in Europe, in light with the EU Green Deal objectives and strategic autonomy.  - When it comes to the implementation of the Stockholm Convention in the EU, the potential inclusion of D4/5/6 in the EU POPs regulation would affect the trade, production, and accessibility of silicones across the globe and hamper the ability of EU downstream users to access silicones. Ultimately, this would hamper value chains established in Europe, in favour of other regions where the access is secured in a timely and affordable manner.  - Before any proposal is presented to the Council of the European Union, the European Commission shall:  - Consider all the available scientific information to understand whether D4/D5/D6 meet the criteria of Persistent Organic Pollutants under the Stockholm Convention.  - Address the technical, legal, socio-economic aspects of a listing of D4/D5/D6 under the Stockholm Conventions as well as any direct and indirect consequences that such a listing would have on silicone manufactures and downstream users. |

|  |  |  |
| --- | --- | --- |
| **114**  **Date:**  2023/08/10 23:58 | **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Verband TEGEWA e.V.  **Org. country:**  Germany  **Attachment:** | **General Comments:**  Verband TEGEWA e. V. is an association representing chemical companies based in Germany, Switzerland and Netherlands manufacturing and marketing inter alia chemicals for leather and textile production and treatment. Auxiliaries used in producing textiles or leather often contain silicone polymers based which are used for finishing, coating, water-repellency and other purposes. with unique properties. TEGEWA strongly believes that the recent European Commission’s proposal to nominate D4, D5 and D6 under Annex B to the Stockholm Convention on Persistent Organic Pollutants does not take full account of the whole body of scientific evidence, should have recognised already applicable or on-going regulatory activities, and puts at risk numerous beneficial uses including in textile and leather production. Therefore TEGEWA fully supports the information provided by Silicones Europe (see also attachment): - When it comes to the implementation of the Stockholm Convention in the EU, the potential inclusion of D4/5/6 in the EU POPs regulation would affect the trade, production, and accessibility of silicones across the globe and hamper the ability of EU downstream users to access silicones. Ultimately, this would hamper value chains established in Europe, in favour of other regions where the access is secured in a timely and affordable manner. - Before any proposal is presented to the Council of the European Union, the European Commission shall: -- Consider all the available scientific information to understand whether D4/D5/D6 meet the criteria of Persistent Organic Pollutants under the Stockholm Convention. -- Address the technical, legal, socio-economic aspects of a listing of D4/D5/D6 under the Stockholm Conventions as well as any direct and indirect consequences that such a listing would have on silicone manufactures and downstream users. |