

Consumer Solutions and Volatile Cyclic Siloxanes

The regulatory environment regarding Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) continues to be dynamic, presenting challenges for many of Grants customers and channel partners.

Grant Industries continues to believe that products containing D4 and D5 are safe when used in accordance with accepted health and safety principles. It's important to note that:

Summary

- No regulations have been implemented in any country at this time and below is the regulatory framework from different governmental agencies regarding D4 and D5. Grant continues to remain steadfast on our position that these materials are safe and we are working with our Industrial partners on defending our position. We are monitoring the regulatory environment in different countries and can advise that D4 and D5 can be safely used in cosmetics. Since these reviews are coming from a concern to aquatic or environmental standpoint, we are supporting the opinion to restrict D4 and D5 to <0.1% wash-off products.
- Grant and the silicone industry associations worldwide continue to work with government and regulatory agencies globally to help them understand the unique nature of D4 and D5.
- Grant and the silicone industry continue to conduct and support health and environmental research about these products.
- Human health risk assessments conducted on D4 and D5 by the Cosmetic Ingredient Review (CIR) Expert Panel, the Australian government, Health Canada and the UK Environment Agency all conclude that these materials do not pose a risk to humans.
- Environmental field research indicates that these materials do not behave as classic PBTs (Persistent, Bioaccumulative, and Toxic) in the environment. Monitoring data shows that D4 and D5 will break down by several pathways and do not accumulate in the food chain.

Resources & Links

Silicones Environmental Health & Safety Center of North America – www.sehsc.americanchemistry.com CES

Silicones Europe - www.silicones-europe.com

Silicone Industry Association of Japan - www.siaj.jp Global Silicones Council - www.globalsilicones.org

Materials and Product Availability

Grant is continually developing new formulations to anticipate customer's needs and to provide you with sustainable innovations.

- We currently have an extensive range of products which can be considered when formulating finished products with low D₄ or D₅ levels. Discuss the options with your Grant contacts, to understand which solutions will work best.
- Current and future options for low D₄ and D₅ formulations include:
 - Elastomers – gels, suspensions, powders, and custom blends
 - Emulsifiers – water-in-oil, water-in-silicone, emulsification enhancers
 - Gum/Fluid Blends – anhydrous and aqueous, vegetable derived.

Grant experts are always available to discuss developments in the regulatory environment and will work with you to identify alternatives that best fit customers' long term business strategies.

Regulatory Updates

Milestone decision in Canada (Board of Review)

Canada's Environment Minister decided in February 2012 to implement the findings of an independent scientific panel that concluded that D₅ is safe for the environment. As a result of the Minister's acceptance of the "Board of Review" (BOR) findings, D₅ will be removed from a proposed list of toxic substances under the *Canadian Environment Protection Act (CEPA)*.

For more than a year, the Board of Review, comprised of a panel of three renowned toxicologists appointed by the Canadian Environment Minister, conducted a comprehensive and multifaceted scientific evaluation using the most current science relating to D₅ and its behavior in the environment. The Board's report, which was released in October of 2011, concluded that "Siloxane D₅ does not pose a danger to the environment or its biological diversity." Furthermore, the Board found that, "based on the information presented, Siloxane D₅ will not pose a danger to the environment or its biological diversity in the future."

While we are encouraged by the positive news in Canada, we continue to work with government and regulatory agencies globally to help them understand the unique nature of D₄ and D₅.

Canada Pollution Prevention Plan – Siloxane D₄ in Industrial Effluents

Environment Canada published a [Notice](#) on June 2, 2012 addressing industrial facilities that manufacture or use D₄ or a mixture containing D₄, where the total quantity of D₄ used or manufactured is equal to or greater than 100 kg during a calendar year, and, as a result of manufacturing or use, the effluent at the final discharge point(s) of the facility contains D₄.

The risk management objective described in the notice is to reduce total siloxane D₄ releases to the aquatic environment from the sum of all persons subject to the Notice by 80%, from the preparation year levels, by the end of the implementation period.

Stockholm Convention List of Persistent Organic Pollutants

In March 2016, the European Commission proposed D₄ be considered as a potential candidate for the Stockholm Convention List of Persistent Organic Pollutants (POP). Any country belonging to this convention can make recommendations of this nature. The proposal was not supported by the European Council at that time.

In April 2017, the European Commission again proposed nomination of D₄ as a potential POP. This proposal was also not supported by the European Council. The deadline for a nomination to be considered by the POP Review Committee in 2017 is May 23rd, 2017.

The aim of the Stockholm Convention is to eliminate or restrict the production and use of POPs. Nomination automatically triggers the listing review process, however, a nomination does not constitute a decision to ban or restrict. The silicone industry will take action, as appropriate, during the process if our substances are nominated for listing and will continue to defend these products in the regulatory arena.

Grant and the industry remain confident that, based upon available scientific data, our products should not be considered POPs under the Convention, although we recognize that there are differing opinions about the characterization of our products.

We continue to work closely with regulators around the world to provide up to date scientific methodology and data, in support of objective, science based assessments. For more information about Persistent Organic Pollutants please visit:

<http://chm.pops.int/Home/tabid/2121/mctl/ViewDetails/EventModID/871/EventID/230/xmid/6921/Default.aspx>

Norway List of Priority Substances

Norway's national target is to eliminate or substantially reduce releases of priority substances. The priority list includes about 30 named substances and groups of substances. In addition, the national target applies to other substances that meet specified criteria. The first version of the priority list was published in 1997. D₄ and D₅ are part of that list; however no levels for change of emissions have been set.

Enforceable Consent Agreement finalized with EPA – Environmental Monitoring Data for D₄

To provide the U.S. Environmental Protection Agency (EPA) with environmental monitoring data on the siloxane D₄, members of the Silicones Environmental, Health, and Safety Center (SEHSC) have begun an environmental monitoring program, [designed in partnership with EPA](#), to assess levels of D₄ in the environment. The data generated in the program will facilitate EPA's environmental risk assessment for D₄, using actual environmental concentrations, rather than predicting concentrations using computer models. This agreement is consistent with our industry's international environmental stewardship efforts to continually assess the environmental footprint of its products.

Monitoring of D₅ was not considered necessary.

US EPA announced D₄ and D₅ as 2013 Priorities for Health Risk Assessment

On May 7, 2012 the U.S. Environmental Protection Agency (EPA) announced the 2012 Integrated Risk Information System (IRIS) agenda and an associated request for scientific information on the health effects that could result as a consequence of exposure to the chemicals on the agenda. D₄ and D₅ were among the chemicals identified in the 2012 IRIS agenda. Initial data gathering has commenced, however a specific start date has not been communicated. The IRIS Program has recently re-prioritized which of these chemical assessments should be initiated in the next few years. Since the release of the IRIS enhancements in July 2013, the IRIS Program has focused on advancing a smaller number of priority assessments while simultaneously implementing recommendations from the National Research Council (NRC). Fifteen chemicals were identified as having the highest priority for assessment and were placed into three groups based on priority. D₄ and D₅ were not identified in any of the groups. The IRIS Program evaluates information on human health effects that may result from environmental exposures to chemicals. The IRIS database includes oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects and cancer assessments.

SCCS publishes opinion regarding use of D₅ in cosmetics applications

The Scientific Committee on Consumer Safety (SCCS), a committee of the EU Commission which provides opinions on health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products and services, published a final opinion (July 2016) on the use of D₅ in cosmetics concluding that, "*The SCCS considers that the use of Cyclopentasiloxane (D₅) in cosmetic products is safe at the reported concentrations, except for use in hair styling aerosols and sun care spray products.*" (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_174.pdf)

Related to styling aerosols and sun care spray products, the conclusion of the SCCS is not necessarily that there is a risk to human health but rather that there is a need for additional refinement of the information. Grant and the silicone industry, recognizing the refinements that have been made to previous draft, still believe that the SCCS opinion does not allow for an accurate and conclusive assessment of the safety of D₅ for its use in hair styling aerosols and sun care spray products. The SCCS opinion is based on assumptions and approaches intended and expected to overestimate exposure and health hazard for these products.

The SCCS also clarified previous statements regarding impurity levels, indicating D₅ may contain traces of D₄ which is classified in the EU as toxic to reproduction. The SCCS considered the presence of D₄ as an impurity in D₅, since D₄ is classified in the EU as toxic to reproduction, category 2, according to Annex VI of Regulation (EC) No. 1272/2008 (CLP-Regulation). The SCCS concurred that there is only a "negligible risk due to D₄ as an impurity of D₅ at the level of the batches used in the [Cosmetics Europe] dossier submitted by the applicant (D₅ purity > 95%)."

Grant continues to believe that products containing D₄ and D₅ are safe when used in accordance with accepted health and safety principles, and is working with the industry to contribute to the scientific discussion and recommends that further specific refinements be made to the exposure assessment for these products.

Grant products containing various levels of D₄ and D₅ are available for use. Grant will continue to support our customers with products that meet our customer needs while meeting global regulatory requirements.

European Commission proposes inclusion of Octamethylcyclotetrasiloxane (D₄) in Annex II of the Cosmetics Regulation (EC) N° 1223/2009

The European Commission has proposed inclusion of D₄ in Annex II in accordance with Article 15 because of its classification as a CMR category 2. The inclusion of D₄ on Annex II does not prevent the use of other siloxane or silicone polymers in which D₄ may be present as an impurity, provided that the siloxane or silicone polymer is safe for use in a cosmetic product in accordance with Article 3 of the Cosmetics Regulation.

Update: UK Targets D₄/D₅ Restriction as Risk Management Option under REACH

In April 2015, under the REACH regulatory framework, the UK authorities submitted a proposal for a restriction on the uses of D₄ and D₅ in wash-off personal care products in the EU.

In March 2016, the Risk Assessment Committee (RAC) issued a final opinion supporting the proposed restriction under Annex XVII of REACH. The RAC also concluded that D₄ meets the REACH Annex XIII criteria for both a Persistent Bioaccumulative and Toxic (PBT) and very Persistent very Bioaccumulative (vPvB) substance and D₅ meets the REACH Annex XIII criteria for a vPvB substance.

The Committee for Socio-economic Analysis (SEAC) issued a final opinion in June 2016 supporting the proposed restriction. On June 11, 2016, ECHA announced that the SEAC adopted its opinion and confirmed SEAC's view that the restriction of the use of D₄ and D₅ in wash off applications should enter into force two years after publication in the official journal.

On 10 May 2017, the REACH Committee adopted, by vote, the EU Commission's legislative proposal with the following restriction text: 'D₄ and D₅ shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0.1% by weight of either substance, after [*date – **twenty four months after the entry into force of this Regulation***]'. For the purposes of this entry, 'wash-off cosmetic products' means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) 1223/2009 that, under normal conditions of use, are washed off with water after application."

The next step in the restriction process is 'scrutiny' by the European Parliament and the European Council which is expected to be completed in the next 3 months. The expected entry into force of the restriction is end of 2019 at which time all actors that place on the market products that are within the restriction scope will have maximum twenty-four months to comply with the requirements.

Grant reputable scientists, and the silicone industry do not agree with the assessment that D₄ is PBT and vPvB and D₅ vPvB, and do not believe there is need to restrict the uses of D₄ and D₅ in any application. Whilst recognizing that there are differences in global scientific opinion on how to use weight of evidence analysis to evaluate PBT and vPvB properties, as well as differences in regional regulatory criteria, Grant and the silicone industry are committed to the successful implementation of the restriction.

Grant products containing various levels of D₄ and D₅ are available for use. Grant will continue to support our customers with products that meet our customer needs while complying with global regulatory requirements.

European Commission Requests ECHA to Prepare Expanded Restriction on D₄ and D₅

In December 2016, the European Commission requested ECHA to prepare a restriction proposal concerning the use of D₄ and D₅ in leave-on cosmetic products and other consumer and professional products – not covered in the earlier restriction proposal.

On April 13, 2017, ECHA posted the restriction intention to the public Registry of Intentions. The proposed scope of restriction to be evaluated covers the use of D₄ and D₅ in leave on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D₄/D₅ in concentrations > 0.1%. ECHA is expected to finalise their evaluation by April 2018. The dossier will contain the justification and recommendations to further restrict or not.

A call for evidence (Call) on the new possible restriction on D₄ and D₅ started 3 May 2017 and will finish 3 August 2017. ECHA launched this Call to identify the current uses of D₄/D₅ in consumer and professional products, the content of D₄/D₅ and emission rates from these products, as well as other relevant information for the preparation of a possible Annex XV restriction dossier. Interested parties such as companies (manufacturers, suppliers, distributors, importers etc.) trade associations, scientific bodies and any other stakeholder holding relevant information are encouraged to respond now.

This call does not replace the public consultation that is organized by ECHA at the start of any restriction process (potentially July to December 2018 if a restriction proposal is submitted in April 2018).

Please find the link to further background information. <https://echa.europa.eu/addressing-chemicals-of-concern/restriction/calls-for-comments-and-evidence/-/substance-rev/16501/term>

Grant and the silicone industry maintain that the proposed restriction is not warranted. This position is supported by the conclusions of the European Chemicals Agency (ECHA)¹ Risk Assessment and Socio Economic Assessment Committees and is in agreement with the UK's proposal to restrict D₄ and D₅ only when used in wash-off personal care products (identified as the main source of emissions to the aquatic environment).

¹ RAC and SEAC opinion on Annex XV restriction report <https://echa.europa.eu/documents/10162/7209f47e-58a0-4fa7-9890-11366f5aa4e9>

California's Safer Consumer Product Regulation

The California Safer Consumer Products regulation requires that manufacturers producing certain products containing selected chemicals review those products to determine if there is a safer alternative chemical.

The regulation implementation will take place in two phases. The Chemicals of Concern for the first set of 5 Priority products will be selected from a reduced list (Initial List) of about 230 Candidate Chemicals. The Chemicals of Concern in the second phase of Priority Products will be selected from a set of about 1,200 Candidate Chemicals (Full List).

D₄ and D₆ were on the Initial List of chemicals, but were not selected to be in the first set of 5 Priority Products.

D₅ was not on the Initial list, but it is on the Full list. This means that D₅ will not be targeted at this time, but may be in future additions of Priority Products.

The inclusion of a chemical on these various lists does not necessarily mean there is any risk of harm posed by their use in consumer products. The lists announced are simply intended to inform consumers and manufacturers about the chemicals in products that may receive further analysis.

Once a set of Priority Products has been approved, the manufacturers of these products will need to go through the Alternative Analysis process to determine if the specified Chemical of Concern can be replaced with a less hazardous chemical.