

Brussels, November 2014

## Holding Statement

*Brussels (12 November 2014)* – The following statement can be attributed to CES Silicones Europe following the United Kingdom's (UK) recent registration of its intent to submit a restriction proposal under the European Union's chemicals management program (REACH). The restriction would call for limiting D4 and D5 in rinse-off personal care products. As part of the restriction preparatory phase, ECHA has just launched a Call for Evidence encouraging stakeholders to provide information that would assist the Member State Committee assess whether the REACH Annex XIII criteria for PBT/vPvB are met for these substances. The proposed restrictions have not yet been finalised nor approved and may be further amended based on information provided in response to this call for evidence or subsequent public consultation.

The silicones industry does not believe there is a need to restrict the use of D4 or D5 in any application, since the REACH Annex XIII criteria call for the thorough application of a Weight of Evidence approach in addition to meeting the numerical criteria, and the Weight of the Evidence of the currently available data does not warrant any regulatory action. In addition the concentrations of these materials that have been measured and continue to be measured in the environment via a global voluntary monitoring program are substantially below the levels that might pose a risk to the environment and/or humans. Imposing restrictions would unnecessarily hamper international trade, economic growth, stifle innovation and would not be proportionate to the lack of risk.

The existing criteria for assessing whether a substance is PBT<sup>1</sup> or vPvB<sup>2</sup> under REACH do not allow for accurate evaluation of silicon-based substances. Current criteria over-predict the potential bioaccumulation and concentration of these substances in the environment. In our view and the view of many leading scientific experts, D4 and D5 are not PBT or vPvB. Latest advancements in bioaccumulation evaluation support that all available laboratory and field derived bioaccumulation data should be considered collectively with environmental exposure findings to make a final determination of bioaccumulation. The weight-of-evidence indicates that these substances are safe for human health and the environment in their intended uses. Environmental monitoring data collected by the global silicones industry and governmental regulatory agencies demonstrate that D4 and D5 are not found at, nor will be found at, levels that pose a risk to the environment.

Environment Canada, having reviewed the environmental data available for D4, has not imposed any product concentration restrictions on the use of D4 in any application. In addition, a comprehensive, risk-based assessment of the data conducted by an

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<sup>1</sup> Persistent, Bioaccumulative, Toxic (PBT)

<sup>2</sup> Very Persistent, Very Bioaccumulative (vPvB)

independent, group of leading scientific experts selected by the Canadian Government concluded that D5 does not pose a risk to the environment now, or in the future.

The safety of D4 and D5 in personal care products has also been confirmed by independent expert panels, including the European Scientific Committee for Consumer Safety, the United States Cosmetics Review Panel, and Health Canada. The silicones industry will continue to work with U.K. regulatory authorities on the development of regulatory assessments and associated management measures that minimize environmental impacts, and that facilitate innovation, job-creation, and economic growth.

### **About CES – Silicones Europe:**

We are a non-profit trade organisation representing all major producers of silicones, silanes and siloxanes in Europe. CES is a sector group of the European Chemical Industry Council (CEFIC), which is both the forum and voice of the European chemicals industry. We provide health, safety and environmental information and are dedicated to the principles of Responsible Care.

**For more information, please visit our Cyclosiloxanes Information Centre at [www.cyclosiloxanes.org](http://www.cyclosiloxanes.org) or contact:**

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