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DG SANTE  
European Commission  
Building F101  
1049 Bruxelles

CC: [REDACTED]  
Director-General of the Joint Research Centre

Brussels, 7<sup>th</sup> September 2017

**Subject: Miscalculation found on a specific substance in the report screening chemicals to identify potential endocrine disruptors according to different options in the context of an impact assessment.**

Dear Sir, Dear Madam

CES - Silicones Europe (CES) is a non-profit trade organisation representing all major producers of silicones in Europe. We provide information on silicones from a health, safety and environmental perspective.

We are writing to bring to your attention a miscalculation we found in the [Joint Research Centre/lbf/Benaki screening report](#) for the identification of potential endocrine disruptors (ED)<sup>1</sup> concerning a specific REACH chemical. This report contains a list of chemicals assessed against the four legislative options originally envisaged by the Commission. Octomethylcyclotetrasiloxane (also known as 'D4', entry 5382 page 293) is displayed as 'ED' under the four options, even when potency is considered. This is of major concern to the Global Silicones Industry since our data do not suggest this would be the case.

With a view to understanding the basis for the JRC's assessment, we requested the supporting data from the Commission via the 'request for document disclosure' procedure. We thank the Commission for providing us the excel spreadsheet containing the data.

An analysis of this document showed that

- the wrong trigger value for classification has been used by the JRC and/or their consultants when assessing the potency option (based on the trigger concentration for STOT-RE<sup>2</sup> under GHS/CLP). The gas trigger value has been used instead of the vapour concentration. As described by Meeks et. al., 2007, "rats were exposed *via vapor inhalation* up to 700 ppm D4"<sup>3</sup>. Since this was a vapour exposure **a conversion from ppm to mg/L should have been applied before comparing the study results with the trigger concentration. This results in a miscalculation of a factor > 1000:**
  - JRC's assessment: effects seen at 700 ppm which is below the classification value of 1500 ppm for gas. Concluded 'ED'.*

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<sup>1</sup> Full title of the report: Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment (2016)

<sup>2</sup> Specific Target Organ Toxicity - Repeated Exposure

<sup>3</sup> Meeks Robert G. *et al.*, 'An inhalation reproductive toxicity study of octamethylcyclotetrasiloxane (D4) in female rats using multiple and single day exposure regimens', *Reproductive Toxicology* **23** (2007), 192-201.

- The vapour classification threshold corrected for duration is 6 mg/L. It is necessary to convert the 700 ppm to mg/L before comparing with the classification threshold. 700 ppm D4 converted to mg/L is 8492 mg/L, which is considerably higher than the 6 mg/L threshold and therefore leads to 'no classification' under this option. The JRC and/or their consultants used a mechanistic study as a reference for comparing effects levels with the classification threshold. A longer duration more definitive reproductive study exist, namely a two-generation reproductive study (Siddiqui et al., 2007.)<sup>4</sup>. This study confirms that D4 does not qualify as ED under this option, adding to the weight of the evidence related to animal studies.

While it is clear that the JRC report does not constitute a formal regulatory assessment, the list of substances from the report has already been used beyond its intended purpose (e.g., by France recently) for developing the French list of ED pesticide products. This highlights the importance of correcting this assessment.

We would be grateful if the European Commission could clarify how such correction could be made.

We thank you in advance for your help and remain at your disposal for any further information.

Yours sincerely,



Secretary General  
CES – Silicones Europe

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<sup>4</sup> Siddiqui Waheed H. *et al.*, 'A two-generation reproductive toxicity study of octamethylcyclotetrasiloxane (D4) in rats exposed by whole-body vapor inhalation', *Reproductive Toxicology* **23** (2007), 202-215.