**Response to comments on the SEAC draft**

**Opinion**

**on the Annex XV dossier proposing**

**restriction** **TDFAs: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives**

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**EC number:** - **CAS number:** -

**15 June 2017**

Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. The restriction proposal covers (see chapter C of the background document) alternatives to the use of mixtures containing TDFAs and organic solvent in consumer sprays, including:

(a) alternative application methods (such as brush, roller or cloth);

(b) water-based mixtures containing TDFAs (mainly for absorbing surfaces);

(c) polyfluoroalkyl trialkoxysilanes chains different from octyl and;

(d) products without fluorotrialkoxysilanes.

Please provide information on uses of these alternatives, risks from the alternatives and on socioeconomic aspects (e.g. further details on costs), especially related to the possible health impacts from (c) and (d). SEAC assumes that the alternatives in (a) and (b) will not lead to any health impacts unless contrary information is received during the public consultation.

1. The restriction proposal (see chapter E of the background document) contains an alternative restriction option with a higher, risk based concentration limit of 800 ppb, instead of 2 ppb. This option would allow the placing on the market of products that may contain TDFAs as impurities. If products containing impurities of TDFAs above 2 ppb are restricted, then the compliance costs of the restriction may rise due to reformulation costs.

Please provide evidence on the presence of TDFAs as impurities in consumer products within the scope of the proposed restriction. At what concentrations are these impurities present? How much will it cost to re-formulate these products to avoid TDFAs being present as impurities?

1. RAC has proposed that professional products containing mixtures of TDFAs and organic solvents shall be labelled “only for professional use”.

Please provide information related to the cost and practicability of including such a label.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 308 | **Date/Time:** 2017/05/19 10:25  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  CES - Silicones Europe  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  On re-examination of the incidents with spray applications, neither in literature of the last 10 years, nor Prof. Pauluhn (an internationally well-known inhalation expert), could establish any single cause for the inhalation toxicity observed (pressure, droplet size, additives, formulation, solvents, droplet size all together are the relevant parameters). Instead, these investigations proved very clearly that restrictions on individual formulation components do not lead to any reduction of risk (see reference list in “Perfluorosilanes in Spray Applications for Consumers (II)”; already submitted to the Public Consultation for this restriction proposal):  This restriction cannot be considered as in line with the ‘precautionary principle’ since it does not appear to solve the problem: the substance alone does not cause the risk, rather it is the combination of spray equipment, pressure and formulation. Therefore, the proposed restriction does not control the root of the problem. (see reference list in “Perfluorosilanes in Spray Applications for Consumers (II)”; already submitted to Public Consultation”) |
| **Specific information 3:**  We do not Support the restriction of the substance as the substance alone s not the root of possible Inhalation to of spray applications as explained in the lieterature of the last 10years. But the manufacturer recommends to note in the safety data sheet that the substance should not be used in consumer spray applications AND to communicate this limitation on use down the supply chain. |
| **SEAC Rapporteurs response:**  Thank you for your comments and for collecting and reporting the comments of your associates. However, in our view, there is no additional information in your comments that calls for any changes of the SEAC opinion. |
| 316 | **Date/Time:** 2017/05/22 18:18  **Type:** MemberState  **MS name:**  Sweden | **Comments on the SEAC draft opinion:**  As stated in previous public consultation Sweden supports the proposal from Denmark to ban the use of TDFAs in mixtures containing organic solvents placed on the market or used in spray products for consumers. Sweden agrees that the identified risk is severe and that this should be handled on a Union-wide basis.  Sweden agrees with SEAC that one strong argument is that this restriction will prevent that such spray products would be placed on the Union market now or in the future. |
| **SEAC Rapporteurs response:**  Thank you for your comment. |