**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restrictions on

**(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**

**Non-confidential**

**ECHA/RAC/RES-O-0000001412-86-142/F**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| **Substance name** | **EC number** | **CAS number** |
| (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 | - | - |

16 March 2017

General Comments and answers to specific information requests

## Specific information requests:

1. Types of product and content: Please provide any relevant information on impregnation sprays for consumers currently placed on the EU market containing TDFAs and organic solvents. More specifically, please indicate:
   1. whether the product is used for absorbing (leather, textiles, plaster, brick etc.) or non-absorbing substrates (e.g. glass, metal, tiles, ceramics) and to which quantities in the EU;
   2. which TDFA and which organic solvent is used in these products and what are the risk management measures in place for the products identified (e.g. labelling);
   3. if the product is currently available on the EU market please clarify when the product has been placed on the EU market, (if the product has been removed from the market, which period in the past was it available?).
2. Information on adverse effects and respirable fractions: For those products referred to in question 1, please provide information on:
   1. reports of adverse health effects (potentially) linked with TDFAs and organic solvents (e.g. incident and study reports);
   2. studies that tested aerosol/pump sprays, containing organic solvents, to estimate the percentage of the inhalable fraction of the resulting aerosol and the percentage of the solvent that is inhaled? Please also specify the type of spray nozzle. Priority should be given to studies that looked at the inhalable fraction in the primary aerosol and following rebound effects from a hard surface (non-absorbing);
   3. how the properties of the spray container “nozzle” can be modified to reduce the % of inhalable fraction or the rebound effect from spray products containing organic solvents.
3. Alternatives to TDFAs in impregnation sprays: The following questions relate to the alternative substances (to TDFAs with organic solvents) used as impregnation spray products for consumers (or mixtures to be used for this purpose) currently available in the EU market, including water-based TDFAs products.

Please provide the following information for each alternative mentioned: i) product name, ii) their ingredients (and concentrations thereof) , iii) the scope of application (absorbing or non-absorbing materials and intended uses with examples), iv) the type of application (aerosol, pump or trigger spraying) and v) if possible, specify the type of spray nozzle.

* 1. Do you have information on the risk profile (health/environmental risks) of the alternatives? This information could include particle size distributions of the primary aerosol atmosphere (generated during the spray process) and if relevant for non-absorbing uses, the particle size distribution that is generated as a rebound effect from the non-absorbing surface. In addition any knowledge of health effects (pulmonary diseases or any others) and reported incidents caused by the use of polyfluorooctyl (or polyfluorohexyl) trilalkoxysilanes in spray products or by the use of alternative spray products.
  2. Do you have information on the technical and economic feasibility of those alternatives?

1. Please provide information on the potential socioeconomic effects for companies due to a potential restriction of TDFAs (with organic solvents) in impregnation sprays. These effects could include:
   1. costs to businesses (e.g. due to reformulation, adaptation of production process, higher cost price of ingredients),
   2. information on societal costs (e.g. loss of employment), in particular to SMEs, and
   3. benefits to human health (e.g. avoidance of health costs).

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1465** | **Date:** 2016/07/25 16:25  **Content:** Hazard or exposure  **Type:** MemberState  **Country:**  Slovenia | **Comment:**  Slovenian Poison Control Centre informed us, that NO POISON CASES for this substances were reported. |
| **Dossier submitter response:**  Thank you for your comment. |
| **RAC Rapporteurs comments:**  Thank you for your comment. |
| **SEAC Rapporteurs comments:**  Thank you for this information. |
| **1469** | **Date:** 2016/08/26 08:49  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** xx  **Org. country:** Germany  **Company name confidential:** Yes  **Attachment:**  confidential  **Privacy comment:** In the dossier you can find information on toxicological properties. This Information is of Commercial interest. The dossier contains Information on the composition of 2 products.We considers this as intelectual properties and is of high commercial interest. | **Comment:**  1) To our opinion a restriction of these substances would not be appropriate to avoid future incidents with spray applications as the cause of incidents is not only the substance as such but also the additional used additives (anti-corrosives, emulgators, solvens etc.) in combination with the spray equipment used.  The most important precondition for a health concern is the generation of very small droplets: "Without fine droplets, no risk".  Reasons, evidence and relevant references are given in the attached dossier. |
| **Answer to specific info request 1:**  1) xx is a producer of this substance, but no manufacturer of spray application products for consumer market. We have not very much direct customers using this substance within formulations for use in consumer sprays. All interested parties would buy this product via distributor or formulators and they are very reluctant in given detailed informations.  This material is a very active ingredient only necessary in low amounts.  Because of this we only can answer in general statements: To use TDFAs you NEED solvents (or solving supporting substances) as the F-containing material is insoluble in water. You have to adapt all formulations to the forseen material. In general aquaous systems are not suitable for non-absorbing materials and very smoth surfaces (more details: s. Dossier attached)  2) Basically all polar solvents are suitable. Details have to be provided by formulators for spray applications  3) The substance is >15 years on the market (globally). |
| **Answer to specific info request 2:**  1) By now we have got no hints or information of cases with pulmonary effects with these substances. To our best knowledge published data on effects of commercially available proofing sprays show no evidence that effects observed are caused by these substances mentioned under “substance name” (we checked this in evaluating with our Marketing and sales team and my literature research).  2) We evaluated for one of our product thr resp, trach, and alveol. fraction including rebound effects with commercial available spray applicators (with a typical Trigger spray we measured: R(inh)=0,063%, R(respirable)=0,007%). We are willing to share this information with relevant authorities (but not via internet). Spraying towards a surface lowers the exposure!!  3) This is a question to the contructor of spray application. But we could show for "typical" trigger pumps produce coarse enough droplets. We made tests with commercial available spray applicators (low pressure, foam former). We are willing to share this information with relevant authorities (but not via internet). |
| **Answer to specific info request 3:**  1) The particle size distribution is not dependant on the F-silane, but from application pressure, nozzle, overall composition. To our best knowledge water-solved TDFAs are not existing as they insoluble in water; hydrolysed substances could be solved in aqueous systems. Solvent solved TDFAs are able to create very thin layers (10-20nm) on very smoth or hard surfaces, like glas, ceramic, metall.  Waterbased F-compounds are used for coarse and/or high absorbing surfaces. We also investigated the rebound effect: This effect is lowering the exposure (we are willing to shar this information, but not via internet)  2) We have no economic information got from this type of application, but F-chemicals are very expensive (and very active) and higher derivatives or more complex F-compounds are even much more expensive |
| **Answer to specific info request 4:**  1) As written before: This type of substance are already very expensive and higher F-compounds are even more expensive as they are complete different products. This product is a very important niche product. A restriction would stigmatize this substance. To our experience: customers try avoid substances in new products which are listed in any restriction list independent on the type of restriction (see also our dossier attached). As a possible hazard of the substance is not the cause on any incident it would not appropriate to restrict this substance. Additionaly: As one of the most important factors for inhal tox (in this context) is the droplet distributution it WOULD NOT AVOID incidents in future. Because of this this a restriction would not be appropiate. |
| **Dossier submitter response:**  Response to comment 1): The purpose of the restriction is to prevent future incidents of intoxication in consumers from spray products containing TDFAs and organic solvents. Since very little information is generally available on the chemical identity of the active ingredients of the spray products involved in the identified incidents and since documentation from animal studies is not available for other combinations than TDFAs and organic solvents the scope is limited to mixtures of TDFAs and organic solvents. This is described in section A.2.1 of the background document (BD). If future studies of spray products show that effects in human incidents can be related to other substances or mixtures, a new restriction proposal should be considered.  As described in section A.2.1 of the BD toxicity depends both on the combination of TDFAs and organic solvent and on the particle size distribution (application method).  Response to answer to specific info request 1:   1. The answer from the respondent supports the description in section A.3 (main uncertainties) of the BD that when the substances are sold via a distributor the information flow in the supply chain is broken – that is the downstream users do not inform the supplier of the exact use of the substance. 2. The answer from the respondent supports the description in section B.1.2 of the BD: volatile organic solvents like ethanol and 2-propanol enhance cross linking and make a good wetting of the substrate. Ethanol is able to penetrate into the material (stone, wood) and infiltrate the material. This means that ethanol will make TDFAs go deeper into the material and the material/substrate will therefore be protected for a longer time even if the material will be changed by abrasion on the surface. In Nørgaard et al. (2014) seven commercially available water-based TDFAs spray products were studied. The products were all products for absorbing surfaces. According to a formulator, a surface modifier (surfactant) has to be added to water-based formulations containing TDFAs to enhance stability. 3. Thank you. This information has been added to section B.2.1.2.   Response to answer to specific info request 2:   1. Thank you for the information. In general poison centres do not know the chemical identity of the substances/mixtures of spray products, which makes it difficult for them to relate incidents to specific substances – it takes hours and hours of laboratory analysis to make this relation when no information on active substances is available on the label or in the SDS. 2. DS agrees that the overall exposure lowers when spraying towards a surface. However, when spraying towards a wall particles with diameters <10µm are generated which is relevant for depletion of the SP-B proteins in the deeper parts of the lungs. The generation of small particles from spraying towards a surface has been studied by among others Vernez et al. (2004) and Nørgaard et al. (2010d). Using the same type of trigger spray Vernez et al. (2004) found toxic relevant concentrations in the <10µm fraction in both a 12 m3 and a 43m3 room from spraying with two different proofing/impregnation formulations (fluorocarbon resin and polyfluoro-acrylat copolymer in combination with organic solvents). When Nørgaard et al. (2010d) extrapolated test data for NFP1 applied by a trigger spray to a 17.4 m3 room, they found concentrations in the <10µm fraction to be 1.4 mg/m3. This concentration is considered relevant for pulmonary toxicity when compared to the DNEL. Of the total amount used 0.0081% were in the relevant <10µm fraction. 3. Thank you for the information, please also see response under 2)   Response to answer to specific info request 3:   1. We note that the respondent supports the statement in e.g. section B.1.2 of the BD that solvent based TDFAs are used on non-absorbing surfaces like glass, ceramic, metal etc. Nørgaard et al. (2014) studied seven commercially available water-based spray products containing hydrolysed TDFAs representing products to be applied on absorbing surfaces. 2. We note that the respondent supports the statement in the BD that prices increase with increasing chain length, but as shown in table 9 of the BD this is not always the case.   Response to answer to specific info request 4:   1. The statement by the respondent suggests that the effect of the restriction on this very narrow scope of a restriction (TDFAs, organic solvents, spray products, consumers) would be broader than just that use of TDFAs (less than 10% of the volume) as a restriction would stigmatise the substances as such and giving incitement of the customers to avoid the substance. However, we have not seen any evidence of that should be the case. In general, some consumers might avoid using fluorinated substances due to the risk for environment, but no information is available showing that listing of a substance on annex XVII is perceived broader than the actual listing. In some cases derogations in restrictions are introduced due to broader societal considerations, lack of alternatives and in these cases some customers would probably try to avoid the substance. To some extent the same might be relevant for TDFAs in combination with solvents in spray products for professionals, where avoidance of this combination would be the first step in the risk reduction hierarchy of control. However for other uses, the targeting of the restriction is based on risk considerations and therefore DS consider this as a matter of communication, also bearing in mind the large number of substances restricted under different types of legislation. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC agrees with the Dossier submitter responses.  RAC acknowledges that the health concern is dependent on the generation of very small droplets (<10µm) this is why the restriction is only targetted at spray products. The restriction will not apply to formulations of TDFAs and organic solvents that are applied using alternative techniques such as brush, roller or cloth.    RAC agrees that the purpose of the restriction is to prevent future incidents of intoxication in consumers from spray products containing TDFAs and organic solvents as well as to ensure that professional users are also aware of the risks if the formulation is applied in aerosol form to ensure adequate workplace risk management measures are in place. |
| **SEAC Rapporteurs comments:**  Thank you for this information. Regarding the prices of alternative f-compounds, SEAC supports the DS statement that the chain length might not be the only endpoint that set the prices of the F-compounds.  Rapporteurs noted the claim for the possible stigmatisation of the TDFAs as a result of the restriction, however SEAC has no information on how this can impact the TDFAs’ sales for the other TDFAs’ uses. |
| **1479** | **Date:** 2016/09/01 12:01  **Type:** MemberState  **Country:**  Sweden | **Comment:**  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. From a socio-economic point of view the negative effects are minor – there are readily available alternatives and negative effects on the market appears negligible.  Sweden understands that it has been difficult to obtain information on occurrence and use, this is not surprising. According to a survey from 2015 lack of available information is substantial for the whole PFAS-group (KEMI report 7/15, http://www.kemi.se/global/rapporter/2015/report-7-15-occurrence-and-use-of-highly-fluorinated-substances-and-alternatives.pdf). Hopefully more information will be obtained during the public consultation.  Sweden also agrees that if future studies show that effects seen in human incidents can be related to animal studies of other mixtures of impregnation spray products, a new restriction proposal should be considered. |
| **Dossier submitter response:**  Thank you for your support. |
| **RAC Rapporteurs comments:**  RAC notes SE support. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. |
| **1482** | **Date:** 2016/09/02 08:58  **Content:** Other socio economic analysis (SEA) issues  **Type:** MemberState  **Country:**  Finland | **Comment:**  Comments on the socio-economic assessment (chapter F):  Basically, the socio-economic assessment is quite marginal and therefore it’s difficult to draw conclusions based on it. For example the dossier is lacking any sort of benefit-cost comparison and even the dossier authors don’t highlight that the benefits would be higher than the costs. Anyhow, we do not exclude that the proposed restriction might be an appropriate measure in this regard, and we suppose that the health effects might be undervalued because in severe incidents the symptoms can possibly last longer than 2-4 days. In addition, all (mild) incidents are surely not reported by the public.  From the technical point of view there are few things to mention. Firstly, presented health costs (table 13) are obviously from different years and therefore cannot be directly summed up. Actually, discounting is entirely missing and there’s neither clarification about when the benefits (and costs) start to realize. There are also a lot of uncertainties in the dossier, and it could’ve been purposeful to address them by a wider sensitivity analysis.  On page 86 it reads that “For the mild incidents the costs have been assumed to 10€”. Where does this amount come from? And what are these costs exactly?  Chapter F.2.1, what has the annual turnover to do with the compliance costs? This could’ve been explained more precisely. Even though it does, the scale of it (54 000€ to 1 200 000€) is so large that it doesn’t seem to be very informative (taking into account that benefits are estimated to 160-460 t€).  Comments on other chapters:  Chapter B.1.2 is lacking information on the exact composition of substances. These compositions would be essential to obtain.  Concerning the estimated incidents, we propose that the uncertainty regarding the extrapolation would be properly stressed out because it’s questionable whether the Danish cases can represent all the cases in the EU. According the information from the Poison Information Centre in Finland there are no reported incidents in Finland.  Overall, we acknowledge that it has been very difficult to sketch a baseline (or any) scenario since there’s significant uncertainty regarding the manufactured and imported amounts let alone the use of TDFAs in different products. However, the dossier is based on limited knowledge and it is a pity that it remains uncertain whether the products on the market include TDFAs or if it’s the TDFAs that causes the health problems.  Other remarks:  The table of tables is missing which complicates a little bit the familiarization with the document. Remark regarding the table of contents is that chapter C.2.3 is listed two times.  Chapter B.5.2.1 is a little bit confusing because there are a lot of “conclusions” without any subheadings. Table 5 on page 38 also confused because there’s an explanation for the sign “+++” but none of the points is classified according to this. On page 71 row 28, the sentence starting “Since it at the same time looks--“ doesn’t seem to make any sense.  Furthermore, here are a couple of comments concerning the links referred. On page 85 the two links (Stationære DRG takster 2015 and PPP) under the footnote 16 are broken. On the same page there’s a reference to the study “RICARDO-AEA 2014” (footnote no. 18) which should be including the referenced page numbers. It’s very inconvenient for reader to search for the information from the long document. Lastly a tiny remark about the labor cost survey (footnote no. 17); there would’ve been a more recent version of it (2012).  http://ec.europa.eu/eurostat/documents/2995521/6313539/3-15122014-AP-EN.pdf/36ae8443-6a22-429a-8e05-6b59088e3155 |
| **Dossier submitter response:**  Thank you for the comments. We agree that a comprehensive traditional benefit-cost comparison is carried out. This is due to lack of information on the actual use (if any) and therefore also lacking information from industry on possible costs. However, in section C, E and F we have introduced a number of building stones in the dossier in case further information should be submitted during the scrutiny of the dossier. Our main argument is risk identified on testing of specific mixtures similar to mixtures which have been withdrawn from the market. On the technical elements:  Health cost baseline year: It is correct that presented health costs (table 13) are from different years and therefore cannot be directly summed up. However, the high estimate for hospitalisation is from 2014 (the low estimate from 2008, (The consumer price index shows 10 % increase in prices from 2008 to 2013)), loss of production from 2013 and the welfare loss estimate from 2010. However, all figures were rounded (e.g. the figure for wellfare loss is estimated to €50, while the two underlying studies showed values of 46 and 57). (The consumer price index shows 10 % increase in prices from 2008 to 2013).  Discounting is missing and unclear when the benefits (and costs) start to realize. Discounting is of minor relevance as the effects are acute and are considered to be closely related to the actual outbreak and the following treatment to be finalised within a short period. Should the information be combined with the estimation of reformulation costs discounting of health cost in the years to come would be relevant.  Estimate of mild incidents – why 10€ – This is DS own estimate. To be compared to the estimate for costs if moderate incidents of 49 €, taken from the French dossier on ammonium salts (which does not include the welfare loss).  What has the annual turnover to do with the compliance costs? We do not have specific information on products on the market which are covered by the proposed restriction. Turnover is the upper bound of profits. Agree, that the information is not very usefull, but it might be considered as a building stone, if more information is submitted by industry.  Chapter B.1.2 is lacking information on the exact composition of substances. See revised BD  Thank you for the editorials. The sub-conclusions in section 5.2.1 refer to the studies described above each sub-conclusion. This has now been clarified in the BD. In Table 5 “+++” is for spray products that are known to be containing mixtures of TDFAs and organic solvents for the general public. It has not been possible to link human incidents with products containing TDFAs with a 100% certainty. According to Koch et al. (2009) it is likely that the 3 Magic Nano products contained a fluorosilane. Since polyfluorooctyl triethoxysilane and polyfluorooctyl trimethoxysilane that belong to the group of TDFAs are commercially available and known to be used in impregnation products like Magic Nano, it is assumed that the 3 Magic Nano products contained TDFAs. Magic Nano is therefore rated as “++” (Most likely to be spray product(s) containing mixtures of TDFAs and organic solvents for the general public). This has now been clarified in the BD.  Regarding the sentence at page 71, the wording has been updated to reflect that we do not think that an amendment to CLP Annex II part 3 on specials rules on packaging is relevant as stand-alone RMO, but that it could be relevant as a supplementary RMO to avoid that products for professionals and industry by mistake are submitted to the general public.  Regarding the updated labor cost survey, this was finalised at the end of 2014, at which time our consultant had delivered the background material. We propose to revise the reference end the text – the figures are not changed as the 2008 figures were already price adjusted by 10% (up to 2013), quite close to the 11% increase in the labor cost survey (EU28) (2012). Actually, as a secondary source <https://www.destatis.de/EN/PressServices/Press/pr/2014/05/PE14_164_624.html> - the average labor cost in EU(27) is estimated to €24 per hour which with the assumed numbers of working hours per day of 7.5, makes an estimate of a working day to be 180 €, exactly the value mentioned in table 15. This information is included in the footnote.  Repaired link to Stationære DRG takster 2015 and PPP:  [http://sundhedsdatastyrelsen.dk/-/media/sds/filer/finansiering-og-afregning/­takster/2015/stationaere-drg­t2015.xlsx](http://sundhedsdatastyrelsen.dk/-/media/sds/filer/finansiering-og-afregning/takster/2015/stationaere-drgt2015.xlsx)  and  <http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tec00120&plugin=1>  Regarding the comment to footnote 18 on whether or not always to include page numbers in references, you could also just use the search function (CTR-F) and e.g. in this case search for “Restricted activity days” |
| **RAC Rapporteurs comments:**  N/A |
| **SEAC Rapporteurs comments:**  Thank you for this comment. We refer to the Dossier submitter answer above, and to the costs and benefits assessment in the opinion. |
| **1485** | **Date:** 2016/09/07 10:15  **Content:** Scope or restriction option analysis;  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** xx Industries  **Org. country:** Germany  **Attachment:** | **Comment:**  Pressure spraying applications and impregnating agents for end users can represent a risk of inhalation toxicity if not used properly. Although it has already become clear in the last 10 years that the hazard is created not just by a single substance or another individual factor. The risk is determined by the following factors: spray nozzle technology, propellant pressure, solvent used, additives, active substance. All these factors together played a clear role as shown after evaluation of the "Magic Nano case" in Germany. In fact there is the need for legal requirements to establish the necessity to investigate these factors and prescribe robust and pragmatic testing procedures for the inhalation-toxic characteristics of the ready-for-sale sprays.  A very good summary of the situation discussed here (Status 2008), including supporting analyses, can be found in a survey study by the Danish Ministry for the Environment in cooperation with the Danish Technological Institute. It also proposes further steps designed to reach the goal.  In this study it became clear that a restriction for the substances listed would not Support the goal to avoid future incidents, because the influences of the spraying equipment used and the overall composition are not taken into consideration |
| **Dossier submitter response:**  As described in section E.1., a restriction is considered the most appropriate risk management option. The suggested pragmatic testing procedures for the inhalation-toxic characteristics of the ready-for-sale sprays would most likely lead to more products being properly classified under CLP. However, no such requirement currently exists under CLP and no such *in vitro* test currently available and it is expected that it will take several years before such test will be available. When a test becomes available it will most likely take several years before such a pragmatic testing procedure would be implemented in the legislation.We focus on restricting products were a risk that is not adequately controlled exists. We see no discrepancy between this and the introduction of a pragmatic testing procedure. |
| **RAC Rapporteurs comments:**  There is currently no legal requirement to test spray formulations before they are placed on the market. RAC agrees that if such testing were undertaken it would have demonstrated a risk. The need to establish legal requirements to test spray formulations before they are placed on the market is a matter for COM & MS consideration however RAC agrees with the dossier submitter that currently no such *in vitro* test is currently available and it is expected that it will take several years before such test will be available. Therefore the proposal to use REACH to manage the risks is considered by RAC as an appropriate legislative instrument. |
| **SEAC Rapporteurs comments:**  Thank you for the information. SEAC shares your view that this restriction would only avoid potential incidents with proofing/impregnation sprays based on mixtures of TDFAs and organic solvents, when it is clear that exposure to sprays with different composition could also lead to human incidents. We refer to the Dossier submitter answer above, and to the most appropriate risk management option discussion in the opinion. |
| **1486** | **Date:** 2016/09/08 17:58  **Content:** Baseline  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** xxx Industries  **Org. country:** Germany  **Attachment:** | **Comment:**  It is the experience of the last 30 years that was not be helpful to avoid future problems with spraying application for consumers to restrict a substance. Because a restriction of a substance do not remove the root cause problem of the accidents.  The essence of the literature cited above and attached:  1)There is a need for EU-wide regulation on spraying products for consumers  2)There is a need for a regulated & enlarged approach for risk assessment on spraying products for consumers  It is highly recommended to perform inhalation testing of the formulated product rather than the individual components.  However, all incidences so far were triggered either by introducing a new spray or by changing one of the parameters in previously safe sprays (e.g. exchange of solvent or physical property of the nozzle). Further re-search in this area is needed and a preventive strategy needs to be developed in order to better evaluate the toxicology of waterproofing sprays to ensure safety of the consumers.  Understanding of particle size distribution is essential for risk assessment.  There is no European-wide safety guidance for the manufacturing of such products.  It is further eligible that a set of information should be deposited at the national appointed body (bodies) according to Art. 45 of the new European Regulation on the Classification, Labelling and Packaging of Chemical Products including at least a complete list of the ingredients of a given formulated product. This will help to improve risk management. |
| **Dossier submitter response:**  Model calculations precented in Appendix 2 of the BD shows that a risk that is not adequately controlled exists for aerosol dispensers. The model calculations and Nørgaard et al. (2009), furthermore, indicates that a risk that is not adequately controlled also exists for trigger and pump sprays containing mixtures of TDFAs and organic solvent. The calculated risk characterisation ratios for aerosol dispensers, trigger- and pump spray drops in the order: aerosol dispensers > trigger spray > pump spray, which indicates the highest risk for application by aerosol dispenser and the lowest for application by pump spray. To handle this risk a restriction is considered the most appropriate instead of waiting for more testing and/or new/updated legislation.  Since very little information is generally available on the chemical identity of the active ingredients of the spray products involved in the identified human incidents and since documentation from animal studies is not available for other combinations than TDFAs and organic solvents the scope of the restriction is limited to mixtures of TDFAs and organic solvents were a risk that is not adequately controlled exists.  In general we support the suggestions for EU-wide regulation on spraying products. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC agrees with the Dossier submitter response. |
| **SEAC Rapporteurs comments:**  SEAC notes that the proposed restriction addresses part of the registered human incidents related to the use of proofing/impregnation spray products. However, the narrow scope of the restriction is grounded on scientific arguments and RAC concluded that there is a risk that is not adequately controlled for the targeted products. From a socioeconomic point of view, unless there are easier and cheaper inhalation tests than the OECD 403 test, that might classify the products regarding its acute inhalation toxicity, a demand for testing each formulated product (the costs for the companies would be around €8 000 per formulated product ([www.productsafetylabs.com](http://www.productsafetylabs.com))) could be disproportionate, taking into account that the major part of the affected companies are SMEs that share an estimated annual turnover between €54 000 and €1 200 000, in accordance of the DS estimation. |
| **1488** | **Date:** 2016/10/06 15:20  **Content:** Hazard or exposure;  Description of analytical methods  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** xxx Industries  **Org. country:** Germany  **Attachment:**    **Privacy comment:** Evonik prepared parts this analytical report together with an 2nd german Company and the german VCI on request of the german BfR. We have the mandate to send these informations to european authorities. | **Comment:**  We are presenting all analytical results prepared on request of the german BfR showing that there is no scientific link between the such called MAGIC-NANO-Case and the TDFAs proposed to be restricted in future |
| **Answer to specific info request 2:**  By now there is no scientific link between the such called MAGIC-NANO-Case or other proofing sprays and the TDFAs proposed to be restricted. Because of the a restriction of this substance Family would not be an appropriate nor an adequate measure. The following can be concluded in summary from the studies presented here:  While the aerosol spray was found to contain only traces of Si and F, it contained relatively large amounts of tin (Sn). None of the studies revealed the presence of a TDFA.  10-40 times more Sn (Sn-organyl?) could be found, raising the question of organo-tin compounds. |
| **Answer to specific info request 4:**  By now there is no scientific link between the such called MAGIC-NANO-Case or other proofing sprays and the TDFAs proposed to be restricted. Because of the a restriction of this substance family would not be an appropriate nor an adequate measure. |
| **Dossier submitter response:**  Based on a Fraunhofer ITEM ICP-MS (Inductively coupled plasma mass spectrometry) test presented in Koch et al. (2009) Industry raises the question of toxicity of organotin compounds that may potentially be present. Koch et al., on the other hand, indicates that the presence of tin in the analysis is due to small amounts of tin persent in the spray can. The Magic Nano Bath & WC pump spray did not contain any tin (Koch et al., 2009). In the XPS analysis (Industry report, 2016) tin oxide and approximately 30 % metallic tin were detected, but no reference are made to organotin compounds.  DS considers the question on the presence of organotin compounds speculative.  According to Koch et al. the low silicon content found by the ICP-MS could be caused by:   * The silane compounds are not within the specified scope of the formulation of the distributor * The silane compounds are volatile and quantitatively lost during sample preparation for ICP-MS analysis   It should be noted that only small amounts of fluorosilanes/TDFAs is needed in impregnation products.  None-hydrolysed fluorosilanes are (semi-)volatile and hydrolysed fluorosilanes in impregnation products are highly reactive which complicate an exact quantification of the substances.  According to Nørgaard none of the five ionisation techniques tested in Nørgaard et al. (2010b and 2010c in the background document) can be designated as being universal for detection of reactive fluorosilanes since each of them is somewhat biased, thus suggesting the use of more than one ionization technique in future analyses of similar reactive samples (Nørgaard et al., 2010c). Furthermore, besides using more than one ionization technique an extra analytical technique has to be added for quantification. This could e.g. be elemental determination of the total amount of silicon Nørgaard (personal communication).  In the Industry report (2016) no silanes are detected by GC/MS (Gas chromatography mass spectrometry).  GC/MS has been tested for identification of TDFAs by Nørgaard et al., and the MS-spectrum only showed the non-hydrolyzed silanes of the products NFP 1 and 2 (personal communication with Nørgaard). He further adds that under the assumption the product doesn’t contain water or that the fluorosilanes can be shaken to an organic solvent it might be possible to get the hydrolysed fluorosilane through the GC column if derivatized with TMS reagent. Only limited information is available on sample preparation in the Industry report (2016), but the sample does not seem to be handled as described by Nørgaard.  If a TDFAs containing product is dominated by hydrolysates and condensates of TDFAs (i.e. no none-hydrolysed TDFAs left in the sample), TDFAs content cannot be detected by GC/MS.  **Overall comment to the Industry report**  In the Industry report (2016) it was not possible to identify the active substance in Magic Nano by any of the analytical methods used. Reactive (fluoro)silanes are known to be difficult to detect. Based on Nørgaard et al. (2010b and 2010c in the background document) Nørgaard suggested to use of more than one ionization technique in combination with MS in analyses of reactive (fluoro)silanes. None of the ionization technique teste by Nørgaard was included in the Industry report.  The key evidence for concluding that Magic Nano doesn’t contain TDFAs in the Industry report (2016) is that the F:Si ratio that does not match that of TDFAs. This would, however, also be the case if Magic Nano, besides TDFAs, contained a non-fluorinated silane.  The Industry report (2016) does, furthermore, not include the SEM-EDX study by Fraunhofer ITEM presented in Koch et al. (2009). This study is the key study in Koch et al (2009) for the assumption that Magic Nano contained a fluorosilane. In 2009 the BfR-commission, who at that time had the 2006 Industry report and Koch et al. (2009) available, agreed with Koch et al. in this assumption.  In the Industry report (2016) the 19F-NMR study indicates the presence of a perfluorinated alkyl-group in the non-volatile Magic Nano residue and the 1H-NMR and IR studies indicates the presence of silane/siloxan. This can be seen as an indication of that Magic Nano might contain a fluorosilane.  The Industry report (2016) indicates that organotin and acrylat could be present in the Magic Nano formulation.This is, however, not justified by the available studies and according to Koch et al. it is likely that the presence of tin in the analysis is due to small amounts of tin percent in the spray can.  Overall, DS does not consider the Industry report (2016) a strong report for the identification of the active substances in Magic Nano and it is highly questionable if it can be used for concluding that Magic Nano does not contain TDFAs. DS agrees with Koch et al. (2009) and the BfR-commission (2009) that it is likely that the active substance in Magic Nano is a fluorosilane. In the Background Document it is furthermore assumed that this fluorosilane belongs to the group of TDFAs. This assumption is based on the fact that polyfluorooctyl trimethoxysilane and polyfluorooctyl triethoxysilane are commercially available and their use is described in several patents on coating/proofing/impregnation products for non-absorbing surfaces like glass and tiles. |
| **RAC Rapporteurs comments:**  Thank you for your comment. RAC agrees with the Dossier submitter responses. Furthermore the Industry representative at the RAC-39 meeting agreed that the presence of organotin compounds in the formulation is questionable. Thus the lung injury of the Magic Nano incidents are unlikely to be associated with organotin compounds. |
| **SEAC Rapporteurs comments:**  Thank you for your information. We refer to the answers provided above. |
| **1490** | **Date:** 2016/10/24 16:23  **Type:** MemberState  **Country:**  Lithuania | **Comment:**  According Lithuania Poison Center not any cases of poisoning or incidents (calls or registered) related with TDFAs substances in spray product. |
| **Dossier submitter response:**  Thank you for your answer. |
| **RAC Rapporteurs comments:**  RAC notes the information from the Lithuania poison centre. |
| **SEAC Rapporteurs comments:**  Thank you for this information. |
| **1492** | **Date:** 2016/11/11 11:47  **Type:** MemberState  **Country:**  Sweden  **Attachment:** | **Comment:** |
| **Answer to specific info request 1:**  For the period 2010-2015 four products containing TDFAs, and which are intended for consumer use, were registered in the Swedish Product Registry, all from the same company. The products contained less than 10% TDFAs. Three of them were based on organic solvents. For 2014 and 2015 the reported quantity for import was zero for all products, showing that there currently are no TDFA-products on the Swedish market for consumers. According to the company this is due to a change in business strategy, from wholesaling of impregnation products to actual performing the impregnation activities. Thus, the substitution of the products was not due to health concerns related to TDFAs.  For more information, please refer to the table submitted as attachment. |
| **Dossier submitter response:**  Thank you for your answer. This supports that not all spray products containing TDFAs and organic solvents was removed from the marked due to the Magic Nano case or the removal of NanoCover (called NFP 1 in the BD) following the animal studies by Nørgaard et al. The removal of the two product (series) was reported in RAPEX in 2006 and 2009 for Magic Nano and NFP 1, respectively. |
| **RAC Rapporteurs comments:**  Thank you for the information. RAC agrees with the dossier submitter response and also notes that since 2014 the product is no longer on the SE market however the purpose of the restriction is to prevent future incidences and ensure workers are alerted to the health concerns when the formulation is applied in spray form. |
| **SEAC Rapporteurs comments:**  Thank you for the information. It is clear now that at least until 2013 there were proofing/impregnation spray products based on mixtures of TDFAs and organic solvents intended for use by the general public, in the EU. |
| **1495** | **Date:** 2016/11/29 11:03  **Content:** Hazard or exposure  **Type:** MemberState  **Country:**  Cyprus | **Comment:**  In Cyprus we dont have any incidents or study reports related to the use or effects of TDFAs and organic solvents in sprays. In addition, there is no information submitted in the Cyprus Chemicals Registry (article 45 CLP)related to such sprays. |
| **Dossier submitter response:**  Thank you for your answer. |
| **RAC Rapporteurs comments:**  RAC notes the response from Cyprus. |
| **SEAC Rapporteurs comments:**  Thank you for this information. |
| **1496** | **Date:** 2016/11/29 13:55  **Content:** Scope or restriction option analysis  Hazard or exposure  Environmental emissions  Information on alternatives  **Type:** MemberState  **Country:**  Germany  **Attachment:** | **Comment:**  Experiments with mice show acute toxic effects when exposed to TDFAs with organic solvents. Similar acute pulmonary effects have also been observed for 8:2 fluorotelomer acrylates. Acute toxic effects (pulmonary distress) have been reported in humans because of the use of impregnation sprays. The compositions of the sprays are more or less unknown, it is however known that fluorinated substances are contained in most of the sprays. From 713 incidents reported only 154 cases are based on the use of TDFAs. Human incidents have also been reported for sprays containing 8:2 fluorotelomer acrylates. The use of 8:2 fluorotelomer substances will most likely be covered by the restriction of PFOA and its related substances.In section C.4.2 it is stated that polyfluorinated triethoxysilanes with a polyfluoroalkychain length different from octyl may have similar toxic effects when aerosolized. If this condensed information is right it seems like the scope of the proposed restriction may be too narrow to prevent further incidents. The restriction only focusses on the 6:2 silanes. It seems however possible (or even most likely) that industry may use even shorter chain polyfluorinated triethoxysilanes which may have similar unwanted toxic effects. Some polyfluorinated triethoxysilanes other than the target TDFAs are manufactured outside of the EU and might be imported in articles (e.g. heptadecafluoredecyl triethoxysilane or nonafluorohexyl triethoxysilane); these compounds might also show unwanted toxic effects when combined with organic solvents.  DE noted that the Dossier Submitter has considered the possibility of a broader restriction covering additional fluorinated substances (other than TDFAs only) in combination with or-ganic solvents and appreciates these activities.  Further comments  B.2: There are inconsistent numbers used for the tonnage of the sprays (or it is not clear how the volumes have been derived: P 21: less than 2-10t/a; page 20: as a maximum 1-10 t/a  Page: 23: conclusion: 20-200 kg TDFA: It is not clear how this number has been calculated/estimated.  B.4 Environmental Fate properties/B7 Environmental hazard assessment and PBT and vPvB assessment:  It is stated that environmental releases are considered neglibible. However, we know especially from the PFOA case that the binding of the polyfluorinated side chains to the polymer backbone (as shown in the figure on page 17) is not complete. That means that unbound residues are still present. Those residues are released easily to the environment. The polyfluorinated fluorosilanes will be degraded to perfluorianted substances in the environment and in biota. Those degradation products will persist for decades and will enrich in the environment. Thus, even small amounts of the released substance may lead to elevated concentrations in the environment. The assessment of short chain PFAS is ongoing by several MS (e.g. ongoing SeV of 6:2 fluorotelomer acrylate and methacrylate). There are hints that short chain PFAS may act as EDs, a subject which is discussed currently in the ED-expert group. Moreover, short chain PFAS enrich in plants (e.g. Krippner et al., 2015 J.AgricFoodChem 63(14)).  Short chain PFAS are very mobile and once emitted into the environment may easily enter water bodies. Studies already show the presence of short chain PFAS in groundwater, which may be a concern for drinking water (e.g. Eschauzier et al., 2013. Science of the Total Environment 458-460; p477-485). Due to their low adsorption potential, it is difficult to remove them from drinking water, even with advances techniques. Occurrence of short chain perfluoroalkyl carboxylic acids has been reported for tap water (e.g. Llorca et al., 2012. Sci Total Environ 431, 139-150).  Interestingly, substances, which can degrade to PFOA, are considered as a major source of PFOA in the environment. The same situation is most likely true for the short chain PFAS, especially because of the use of the substances in sprays emissions into the environment is likely. Moreover, to our knowledge, the manufacturing of PFAS always leads to broad range of substances with different chain lengths. This means that in the sprays not only C6-PFAS are present, but also substances with shorter and longer perfluorinated chain lengths are present as impurities which are released into the environment as well. This fact is stated on page 60 (C4.3) but should maybe already be covered in chapter B.4. and B7.  Thus, we strongly recommend to revise chapter B.4, B.7 and the assessment of the alternatives in chapter C.  B.8.2.2: although there might be no information on TDFA available, other information (see PFOA restriction proposal) could be used to at least state, that a release into the environment during manufacturing is highly expected.  B.8.3.3/4 B.91.1.3: Are you really sure, that during curing polymerisation is 100%? Unbound residues may be released into the air and may be inhaled by humans.  B.9.1.2: reference to the non-existing section B.2.4  Chapter C: There is a reference to the environmental risks described earlier, but the environmental risk and hazard have not been discussed somewhere earlier in the dossier.  C.5.2: please include the environmental concerns for short chain PFAS (see comments under B4) |
| **Dossier submitter response:**  Thank you for your comments.  We agree that 8:2 fluorotelomer acrylates (and side-chain polymers with 8:2 fluorotelomer acrylate derivatives as side-chain) will be covered by the restriction on PFOA and PFOA related substances. Little or no information has been identified on possible inhalatory toxicity of fluorotelomer acrylates with a different chain length (e.g. 6:2 fluorotelomer acrylate). The same is true for fluorosilanes with a different chain length than TDFAs (e.g. heptadecafluoredecyl triethoxysilane or nonafluorohexyl triethoxysilane). However, given the structural similarity with TDFAs it is not unlikely that these substances in mixtures with organic solvents would have some effect on lung surfactants if aerosolised (as it says in C.4.2). As we have no proof of this it is not possible to extend the scope.  Further comments B2:  B.2.2.1: The “…less than 2-20 t/y” refers to the sum of polyfluorooctyl triethoxysilane and polyfluorooctyl trimethoxysilane that are used in spray products. (The number 2-10 t/y is not mentioned in the report)  B.2.1.1: The “…maximum, 1-10 t/y” refers only to polyfluorooctyl triethoxysilane that are used in spray products.  B.2.2.1.4: As mentioned in the report: 1% of 2-20 tons equals 20-200 kg. Each spray is in average assumed to contain 250 ml with a density of 0.79 g/ml (density of 2-propanol) and the average concentration of polyfluorooctyl triethoxysilane is 1.0-1.5%.  The figure 6 800 units is derived by the following equation: 20/0.79\*4/(1.5/100): 6751 = rounded 6800. – 100 000 units is derived by 200/0.79\*4/(1/100): 101265 = rounded 100.000.  Section B.4, B.7, B.8.2.2, B.8.3.3, B.8.3.4, B.9.1.1.3 and C.4.3 of the BD, all related to environmental issues, has been updated. Reference in section B.9.1.2 has been changed to B.4.  Section C.5.2 refers to section B.7 in the updated BD. |
| **RAC Rapporteurs comments:**  RAC notes the questions and agrees with the Dossier submitter responses. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Regarding the tonnage of TDFAs considered in the proposal we refer to the Dossier submitter answer above. |
| **1497** | **Date:** 2016/12/07 16:37  **Content:** Hazard or exposure  **Type:** MemberState  **Country:**  Ireland  **Company name confidential: Yes**  **Attachment:** | **Comment:**  Please note your weblink to Reg 1049/2001 link is still not working to check Art 4. The names of spray products is being withheld until this can be addressed. As NPIC confirmed this information should be treated as confidential. |
| **Answer to specific info request 1:**  yes |
| **Answer to specific info request 2:**  yes |
| **Answer to specific info request 3:**  no |
| **Answer to specific info request 4:**  no |
| **Dossier submitter response:**  Thank you for the information. |
| **RAC Rapporteurs comments:**  RAC notes the cases involving impregnating sprays in IE and health effects observed following inhalation of some impregnating spray. RAC also notes the lack of available information confirming the presence of TDFAs in those products. |
| **SEAC Rapporteurs comments:**  Thank you for the information. |
| **1498** | **Date:** 2016/12/13 12:32  **Content:** Scope or restriction option analysis;  Information on alternatives  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** ChemSec  **Org. country:** Sweden | **Comment:**  We highly support this restriction proposal even if we find it worrying that not also other fluorinated substances with slightly longer/shorter fluorinated tails are included. Also the non-inclusion of condensates (-di, -tri, -tetra) should possibly be revised to be included in the restriction as well.  This form did not accept any additional information to be submitted in the specific questions below! Hence this part is intended to be inserted in question nr 3.  In the assessment of available alternatives, it should be considered the necessity of using the products affected by this restriction. In this case it is indeed highly questionable if consumers would need such sprays hence there is no need of requiring alternatives to be available to implement this restriction. |
| **Dossier submitter response:**  Thanks for your comment.  Since very little information is generally available on the chemical identity of the active ingredients of the spray products involved in the identified human incidents and since documentation from animal studies is not available for other combinations than TDFAs and organic solvents the scope of the restriction is limited to mixtures of TDFAs and organic solvents where a risk that is not adequately controlled exists.  It is important to consider possible alternatives in order to evaluate the impacts. In principle we agree, that even if alternatives might not be available a restriction could be justified. In this case, we have also pointed to the possibility to require assistance from professionals who might access to the spray products containing TDFAs and organic solvents. |
| **RAC Rapporteurs comments:**  Thank you for the comments. RAC agrees with the Dossier submitter response, unfortunately a lack of information on active ingredients has meant the scope of the proposal is only focused on TDFAs and organic solvents. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. Regarding your concern about the alternatives, SEAC considers that alternatives is not a key issue in the SEAC assessment of the restriction proposal once it is clear that there are alternative substances or alternatives application methods available. SEAC does not have any information on consumers’ needs related to the use of these type of products. |