Denmark proposes a restriction 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 (TDFAs) in mixtures with organic solvents in spray products for supply to the general public [1]

Summary

Denmark is proposing a restriction on spray products for supply to the general public if they contain (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 *(abbreviated as TDFAs in this note).* The products should not be placed on the market if they contain TDFAs in a concentration equal to or greater than 2 ppb by weight in a mixture with organic solvents.

The public consultation on this proposed restriction will start on 15 June 2016 and will end on 15 December 2016. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments by 1 September 2015 to assist them in their initial discussions.

Suggested restriction (SCOPE)

TDFAs shall not be placed on the market when contained in spray products for supply to the general public if they are present in mixtures, with certain organic solvents, in a concentration equal to or greater than 2 ppb by weight.

Spray products comprise aerosol dispensers, pump and trigger sprays and mixtures marketed for spray applications.

The proposed restriction will start applying 18 months after the amendment of the REACH Annex XVII comes into force.[2] There are no uses that are proposed to be derogated (excluded) from the scope of the restriction.

Reasons for action

The proposed restriction has been prepared because Denmark has identified a risk for consumers from the use of spray products containing mixtures of TDFAs and certain organic solvents. The products are used to water proof certain articles and include products for both absorbing surfaces (i.e. textile and leather) and non-absorbing surfaces (i.e. tile and ceramics).

Effects have been reported in humans exposed to spray products containing fluorinated polymers and solvents. 708 incidents investigated in the EU during the past three to four decades have demonstrated a relationship between short-term exposure to certain proofing/impregnation sprays and development of respiratory illness which has required

[1] The information note has been prepared based on the Annex XV report prepared by Denmark.

[2] It should be noted that if the Committees will adopt a positive opinion for this restriction proposal in the opinion making process and the Commission will eventually adopt a restriction through the decision making process, then it will take about 4 years from now (considering the mentioned transition period) for the restriction to enter into force

hospitalisation. According to Denmark, about 20 – 40 % of the 708 incidents reported in the EU were most likely spray product(s) containing mixtures of TDFAs and organic solvents intended for the general public.

It is estimated that on annual basis in the EU, 20-200 kg of TDFAs in combination with organic solvents are sold in spray products (approximately 6 800 – 100 000 spray units) that are intended for the general public.

The risk assessment carried out by Denmark for certain mixtures containing TDFAs and an organic solvent (2-propanol) shows a risk that is not adequately controlled when the mixture is applied by aerosol dispensers or pump sprays (whereas similar effects are also expected for trigger sprays because of the size of the droplets produced).

The justification for acting on a Union-wide basis originates from the EU-wide distribution of incidents of lung injuries due to the use of spray products by consumers containing TDFAs and organic solvents. Since there is a need to avoid different legislative requirements in Member States with the risk of creating unequal market conditions and in order to adequately protect EU consumers, a restriction should target imported as well as EU produced spray products intended for the general public.

Consequences of the restriction proposal

The restriction is considered to be effective in reducing the risks for consumers when applying mixtures based on TDFAs and organic solvents even if it is expected to only reduce a part of the incidences of lung injury from the fluorinated based impregnating sprays. According to the restriction proposal, alternative application methods (water-based spray products with TDFAs and spray products without TDFAs) are readily available at similar prices; therefore the negative effects on the market will be marginal. Denmark concluded that when TDFAs in organic solvents are substituted by other substances, the annualised cost of reformulation per formula is €8 000 – 12000. Furthermore, the impact of the proposed restriction on health is estimated to 120 incidents prevented annually, which based on avoided costs related to respiratory diseases is monetized to €160 000 - €460 000. According to Denmark, considering both the negligible costs and the potential health effects, the proposed restriction is considered to be proportionate to the risk.

SPECIFIC INFORMATION REQUESTED

Questions on specific elements of the proposal that would benefit from additional information have been identified and are set out below in the form of specific questions.

Please note that information can be submitted as confidential information if necessary.

Question 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:

(a) 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;

(b) 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);

(c) 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?).

Question 2: *Information on adverse effects and respirable fractions*

For those products referred to in question 1, please provide information on:

(a) reports of adverse health effects (potentially) linked with TDFA and organic solvents (e.g. incident and study reports);

(b) 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);

(c) 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.

Question-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 TDFA products.

Please provide the following information for each alternative mentioned: i) product name, ii) their ingredients (and concentrations thereof)[3], 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.

(a) 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.

(b) Do you have information on the technical and economic feasibility of those alternatives?

[3] This can be submitted as confidential information as necessary.

Question-4: 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:

(a) costs to businesses (e.g. due to reformulation, adaptation of production process, higher cost price of ingredients),

(b) information on societal costs (e.g. loss of employment), in particular to SMEs, and

(c) benefits to human health (e.g. avoidance of health costs).

Comments preferably by 1 September 2016

The opinion making process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 15 June 2016. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 15 December 2015, RAC and SEAC would appreciate receiving comments by 1 September 2016 to assist them in their preliminary discussions on the restriction proposal.

The final opinions of both Committees are scheduled to be available by 15 June 2017. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in ECHA's new Public Consultation Guidance for restrictions
http://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf