

Bollate 23/05/2008

Ref: Solvay Solexis petition dated 1 March 2007- More data needed

We were informed by EFSA that after the evaluation of the data submitted with the documentation referred to Solvay Solexis petition, the Working Group of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) of EFSA has classified Solvay Solexis Substance in the SCF_List 7, because of lack of the data :

1. Information supporting the statement that the sample tested corresponds to a worst case situation: Can the substance quantitatively evaporate during compression molding?
2. Clarification on the procedure used for identification and quantification of migrating oligomers.
 - What in the procedure ensured that there is no loss of the substances to be analyzed during solvent evaporation?
 - Why was ¹H-NMR used, rather than ¹⁹F-NMR?
3. The rationale of the procedure to determine the residual concentration of the substance
 - Is methanol a swelling solvent for the polymer?
 - Why was an extraction solution like that not used for identification and quantification of oligomers?
4. A clear differentiation is needed between intended applications: which ones for elastomers and which for non-elastomers?

As agreed with TNO, we have examined questions 1 and 4 please find below our answer and comments.

1.

Information supporting the statement that the sample tested corresponds to a worst case situation:

“Can the substance quantitatively evaporate during the compression molding?”

EFSA petition dated 1 March 2007 covers specifically the use of Perfluoro acetic acid, α -substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups (Substance REF No: 71943) in the synthesis of TetraFluoroEthylene (TFE) homo and copolymers through a microemulsion polymerization process. The resulting polymers are in form of latexes, latexes are subjected to further process steps which can differ as a function of the final product: solid polymer or concentrated latex.

Melt Processable grades (typically TFE copolymers) are solid polymers produced through the following steps:

- Coagulation of the latex at room temperature



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- Drying at temperatures between 100°C and 150°C
- Pellet extrusion at temperatures 390° - 400°C
- Molding (either via compression or via injection)

Coating grades (typically TFE homo and copolymers) are concentrated latexes obtained through a process involving the following steps:

- Concentration of the latex at temperatures $\leq 80^{\circ}\text{C}$
- Treatment step to eliminate the ionic surfactant (residual content of the surfactant $< 50\text{ppm}$)
- Sintering at temperature $\geq 420^{\circ}\text{C}$

We consider Melt Processable grades process to be the worst case vs Coating grades for the following reasons.

- a) The processing temperatures are lower in the case of the Melt Processable grades. The higher the processing temperature, the faster is the elimination of the surfactant (Substance REF No:71943) from the polymer.
- b) Melt Processable molded articles are characterized by higher thickness. Molded articles typical thickness is 0.25 mm, while the thickness of a coating is up to an order of magnitude lower (from 0.025 to 0.25 mm). It is apparent that the lower the thickness, the easier is the evaporation of the surfactant (Substance Ref No:71943)

The combination of lower processing temperature with higher thickness was orienting our choice towards molded articles

In the case of solid polymer (non coating) Melt Processable fluoropolymer grades are subjected to the same process involving coagulation, drying , pellet extrusion and molding.

Molding can be obtained through compression or injection techniques, the main difference between the two techniques lies in the molding temperature.

We selected to carry out tests on compression molded articles since compression molded articles can be considered the worst case vs the injection molded articles which are processed at higher temperatures:

Compression Molding: Temperatures: 340°C – 380°C

Injection Molding Temperatures: 390°C – 420°C

The lower molding temperature could result in a reduced evaporation of the surfactant (Substance Ref No: 71943). Furthermore, the surface to volume ratio of the compression molded articles used in our testing can be considered as combining a high thickness with an easy migration of possible residual surfactant in the molded article.

Based on the above considerations we can conclude that compression molded articles using melt processable TFE copolymers can represent the worst situation and this is the case of the samples tested: compression molded sheets of [REDACTED].

[REDACTED] is a melt processable TFE polymer = propane, 1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]-, polymer with tetrafluoroethene and trifluoro(trifluoromethoxy) ethene.



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4.

A clear differentiation is needed between intended applications: which ones are for elastomers and which for non-elastomers.

Melts processable fluoropolymers and coating fluoropolymers, mentioned in Solvay Solexis petition, belong to the non-elastomers family.

They are processed in order to produce a wide range of articles:

- tubing, fittings, pipes and valves
- films and antistick coatings on various food contact articles (from tubing to cooking utensils, including frying pans).

Finished articles are intended for repeated use.

Fluoroelastomers belong to the elastomers family, they are processed in order to produce a wide range of articles:

- O-rings, gaskets, expansion joints and gaskets

Should you need further info or details please feel free to contact us

Yours sincerely

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