SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the substance, Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, CAS No 1190931-27-1, for use in food contact materials [1]

EFSA Panel on on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of EFSA deals with the safety assessment of perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, CAS No 1190931-27-1, for use as a polymer production aid during the manufacture of fluoropolymers. Specific migration of the substance was not determined. The specific migration of the substance and the two degradation products in polytetrafluoroethylene film were determined and the maximum potential migrations were 0.4 µg/kg food. The CEF Panel concluded there is no safety concern for the consumer if the substance is only to be used as a polymer production aid during the manufacture of fluoropolymers which are produced under high temperature conditions of at least 370 °C and intended for repeated use in contact with all types of foodstuffs under all contact conditions.

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KEY WORDS

perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]} ammonium salt, CAS 1190931-27-1, acetic acid 2,2-difluoro-2-[[2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl]oxy]- ammonium salt, FCM 1045, food contact materials, safety assessment

[1] On request from the Ministry of Health, Welfare and Sports, The Hague, Question No EFSA-Q-2013-00363, adopted on 20 May 2014.

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SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to the Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs, the CEF Panel received a request from the Ministry of Health, Welfare and Sports, The Hague, for safety assessment of the substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, following a corresponding application submitted on behalf of Solvay Solexis SpA.

The safety assessment of perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, CAS No 1190931-27-1, (FCM substance No 1045), was requested for use as a polymer production aid during the manufacture of fluoropolymers which are produced under high temperature conditions of at least 370 °C and intended for repeated use in contact with all types of foodstuffs under all contact conditions.

Due to the high temperatures (ranging from 380 to 420 °C) applied for manufacture of food contact articles it can be expected that both the substance itself as well as the decomposition products are efficiently removed during thermal processing (high temperature extrusion, baking or sintering) and not present anymore in the final food contact articles.

Specific migration of the substance was not determined. The worst case residual content in polytetrafluoroethylene (PTFE) film manufactured at a low processing temperature was determined and migration was calculated assuming 100 % transfer. The substance was not detectable in the polymer film at a detection limit of 0.06 µg/g; this corresponds to a maximum migration of 0.4 µg/kg food. The two decomposition products were not detectable indicating a maximum potential migration of 0.4 µg/kg food. The calculated migration values obtained from the residual concentration determinations relate to a single use application. Since the final food contact materials and articles are intended for repeated use, the migration, if any, would occur even at a lower level at each usage.

The substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, was tested in three in vitro genotoxicity tests and in one in vivo genotoxicity test. The substance did not induce gene mutations in bacteria nor in mouse lymphoma cells. The substance did not induce chromosome aberrations in bone marrow cells of the rat, when administered at the highest tolerated dose (1250 mg/kg bw). The main decomposition product did not induce mutations in bacteria and did not induce micronuclei when tested *in vitro* in Chinese hamster V79 cells.

Based on the results of the in vitro and in vivo genotoxicity tests a weak clastogenic potential cannot fully be excluded. However, in absence of genotoxicity of other perfluorinated compounds and since the substance and its decomposition products completely disappear during the production process, there is no safety concern.

It is noted that some perfluorinated compounds may show a high potential for accumulation in man. However the proposed conditions of use would lead to a negligible migration. Under these conditions the Panel has no indication for safety concern for this substance.

The CEF Panel having considered the above-mentioned data concluded that the substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, is not of a safety concern for the consumer if the substance is only to be used as a polymer production aid during the manufacture of fluoropolymers which are produced under high temperature conditions of at least 370 °C. The final materials and articles are intended for repeated use in contact with all types of foodstuffs under all contact conditions.

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BACKGROUND AS PROVIDED BY THE LEGISLATION

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA´s opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[4].

According to this procedure the industry submits applications to the Member States competent Authorities which in their turn transmit the applications to the EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the SCF guidelines for the "presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation" (EC, 2001).

In this case, EFSA received an application from Ministry of Health, Welfare and Sports, The Hague, requesting the evaluation of the additive perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt with the CAS number 1190931-27-1 and the FCM substance No 1045.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food EFSA is asked to carry out an assessment on the risks related to the indented use of the substance and to deliver a scientific opinion.

[4] This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, p.38

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ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the Ministry of Health, Welfare and Sports, The Hague, to evaluate the safety of perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, with a CAS No 1190931-27-1 and FCM substance No 1045. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2013-00363. The dossier was submitted on behalf of the applicant Solvay Solexis SpA.

2. General information

According to the applicant, the substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, is used as an emulsifier/dispersing agent during the polymerization process of fluoropolymers such as tetrafluoroethylene homopolymer and others. These fluoropolymers are processed to produce a range of food contact articles such as fittings, valves, tubes, sheets, pipes, tapes as well as cast films and antistick coatings on cooking utensils. Manufacture of these articles includes high temperature treatments during extrusion, baking or sintering at 380 °C and higher for several minutes. All articles are intended for repeated use in contact with all types of foodstuffs.
The substance has not been evaluated by the SCF or EFSA in the past.

3. Data available in the dossier used for this evaluation

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (EC, 2001).

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on thermal treatment during manufacture of final food contact polymer
- Data on intended use and authorisation
- Data on residual content and estimation of migration of the substance
- Identification, quantification and data on/estimation of migration of impurities and of two decomposition products

Toxicity data:

- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vivo* mammalian chromosomal aberration test
- Bacterial gene mutation test on the major decomposition product
- *In vitro* micronucleus test on the major decomposition product

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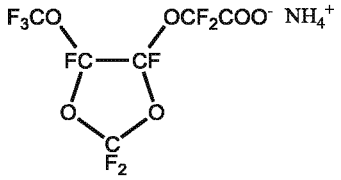
4. Evaluation

4.1. Non-toxicolobical data

Chemical formula and structure: $C_6H_4O_6NF_9$



The substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, CAS No 1190931-27-1, has a molecular weight of 357 Da and is freely soluble in water with a log Po/w of -0.38 at 22 °C. The substance is thermally unstable and starts to decompose at 138 – 140 °C with complete decomposition at 230 °C. The two volatile degradation products have been identified and physico-chemically characterized.

Due to the high temperatures (ranging from 380 to 420 °C) applied for manufacture of food contact articles it can be expected that both the substance itself as well as the decomposition products are efficiently removed during thermal processing (high temperature extrusion, baking or sintering) and not present anymore in the final food contact articles.

Specific migration of the substance was not determined. Instead, the residual content in a polytetrafluoroethylene (PTFE) film with a thickness of 60 µm was determined as a worst case sample manufactured at a low processing temperature (370 °C) and time (2-7 min), and the maximum migration was calculated assuming 100 % migration. The substance was not detectable in the polymer film at a detection limit of 0.06 µg/g, which taking into account the thickness and the density of the polymer translates into 0.4 µg/6 dm². Applying a surface-to-volume ratio of 6 dm² per kg food, this corresponds to a maximum migration of 0.4 µg/kg food.

The maximum specific migration of the two decomposition products was also estimated via determination of their residual concentration in the film sample and 100 % migration assumption. Both degradation products were not detectable in the polymer at detection limits of 0.045 mg/6 dm² and 0.001 mg/6 dm², respectively, which is equivalent to 45 µg/kg and 1 µg/kg food. Due to the high detection limit for the major decomposition product a migration test was carried on the same test film and using 3 % acetic acid and olive oil as food simulants at contact conditions of 4.5 hours at 100 °C and 3 hours at 175 °C, respectively. In both cases the decomposition product was not detectable at 0.4 µg/6 dm² corresponding to 0.4 µg/kg food.

The calculated migration values obtained from the residual concentration determinations relate to a single use application. Since the final food contact materials and articles are intended for repeated use, the migration, if any, would occur at a even lower level at each usage.

Concerning the impurities of the substance, the major impurities (ca 2 %) are structurally related to the substance itself and are expected to decompose thermally in an analogous way. The minor impurity (ca 0.7 %) is a side product of the synthesis of the substance and is expected to be volatilised and lost during the high temperature processing conditions of the fabricated articles.

4.2. Toxicological data

The substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, was tested in three in vitro genotoxicity tests and in one in vivo genotoxicity test. The substance did not induce gene mutations in bacteria (Salmonella typhimurum strains TA1535, TA1537, TA98 and TA 100 and in Escherichia coli WP2 uvrA) nor in mouse lymphoma cells (L5178Y/TK+/- assay).

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However, in a chromosomal aberration assay in Chinese hamster ovary cells in vitro, the substance demonstrated a weak potential for clastogenicity. Therefore, perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, was tested in the in vivo mammalian bone marrow chromosome aberration test. The test substance did not induce chromosome aberrations in bone marrow cells of the rat, when administered at the highest tolerated dose (1250 mg/kg bw). The Panel noted that this test was not fully conclusive because there was no evidence that the target tissue was exposed.

The main decomposition product was tested for the ability to induce gene mutations in bacteria (Salmonella typhimurum strains TA1535, TA1537, TA98 and TA 100 and in Escherichia coli WP2 uvrA). No reverse mutations were induced by this test substance. In an additional test, the main decomposition product did not induce micronuclei when tested *in vitro* in Chinese hamster V79 cells.

Based on the results of the in vitro and in vivo genotoxicity tests a weak clastogenic potential cannot fully be excluded. However, in absence of genotoxicity of other perfluorinated compounds (EFSA CEF, 2010, 2011a, 2011b, 2012) and since the substance and its decomposition products completely disappear during the production process, there is no safety concern.

It is noted that some perfluorinated compounds may show a high potential for accumulation in man. However the proposed conditions of repeated use would lead to a negligible migration. Considering the low exposure and the chemical structure, the Panel has no concern with respect to accumulation potential of this substance.

CONCLUSIONS

The CEF Panel having considered the above-mentioned data concluded that the substance perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt, is not of a safety concern for the consumer if the substance is only to be used as a polymer production aid during the manufacture of fluoropolymers which are produced under high temperature conditions of at least 370 °C. The final materials and articles are intended for repeated use in contact with all types of foodstuffs under all contact conditions.

DOCUMENTATION PROVIDED TO EFSA

1. Perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt. April 2013. Submitted on behalf of Solvay Solexis SpA.

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GLOSSARY

CAS	Chemical Abstract Service
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
FCM	Food Contact Materials
Po/w	Partition Coefficient octanol-water
PTFE	polytetrafluoroethylene
SCF	Scientific Committee on Food

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