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SCIENTIFIC OPINION

Statement on the safety assessment of the substance silicon dioxide, silanated, FCM Substance No 87 for use in food contact materials [1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The substance silicon dioxide, silanated, with FCM substance No 87, is authorised for use as an additive in all types of plastics, without restriction. The re-evaluation of the substance was requested based on the fact that the substance has always been produced on the basis of synthetic amorphous silicon dioxide in nanoform. Information on the basic (untreated) silicon dioxide, the surface treated silicon dioxide, silanated, and a study investigating the migration potential of the silanated silicon dioxide were provided. Having examined the information provided, the CEF Panel concluded that the information provided demonstrates adequately the absence of isolated primary nanoparticles in the basic silicon dioxide and in the silanated silicon dioxide since only aggregates larger than 100 nm along with larger agglomerates were observed using two independent measurement techniques, one of which was transmission electron microscopy (TEM). The particle size range was not affected when the silanated product was incorporated into a low density polyethylene film at 3 % w/w. Furthermore, there was no detectable migration of silicon dioxide, of any particle size, from this film into appropriate food simulants. Therefore at the particle sizes reported, the substance silicon dioxide, silanated, does not raise a safety concern for the consumer in the currently authorised conditions of use.

KEY WORDS

silicon dioxide, silanated, FCM substance No 87, safety assessment, evaluation, nanoparticles

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[1] On request from Commission, Question No EFSA-Q-2013-00562, adopted on 21 May 2014.

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SUMMARY

The EU Plastics Regulation 10/2011 which came into force on 1 May 2011 required that all materials in nanoform to be used for food contact materials must be specifically approved and specified under Annex 1 of the regulation. 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 Commission, for safety re-evaluation of silicon dioxide, silanated, following information received from EVONIK Industries AG.

The substance silicon dioxide, silanated, with FCM substance No 87 is authorised for use as an additive in all types of plastics, without restriction. The re-evaluation of the substance was requested based on the fact that the substance has always been produced on the basis of synthetic amorphous silicon dioxide in nanoform.

Information on the basic (untreated) silicon dioxide, the surface treated silicon dioxide, silanated, and a study investigating the migration potential of the silanated substance were provided. Having examined the information provided, the CEF Panel concluded that the information provided demonstrates adequately the absence of isolated primary nanoparticles in the basic silicon dioxide and in the silanated silicon dioxide since only aggregates larger than 100nm along with larger agglomerates were observed using two independent measurement techniques, one of which was transmission electron microscopy (TEM). The particle size range was not affected when the silanated product was incorporated into a low density polyethylene film at 3 % w/w. Furthermore, there was no detectable migration of silicon dioxide of any particle size from this film into appropriate food simulants. Therefore at the particle sizes reported, the substance silicon dioxide, silanated, does not raise a safety concern for the consumer in the currently authorised conditions of use.

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BACKGROUND AS PROVIDED BY THE COMMISSION

Silicon dioxide, silanated (FCM substance No 87, PM/REF 86285) was authorised in 1999 to be used as an additive for the manufacture of plastic food contact materials and is currently listed in the Union list in Annex I of Commission Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with foods1, without any restrictions or specifications.

The authorisation for the use of silicon dioxide, silanated, was granted on the basis of a positive opinion given by the Scientific Committee on Food (SCF) in 1996 in the 67th working group meeting.

In accordance with Article 11(5) of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, the company EVONIK Industries AG informed the Commission that the substance has always been produced on the basis of synthetic amorphous silicon dioxide in nanoform. In December 2012 the company supplemented the information with information on the surface treated silicon dioxide, silanated, and basic silica (as authorised under FCM substance No 509 by Regulation (EU) 10/2011) and a study investigating the migration potential of the substance.

In view of the new information supplied regarding silicon dioxide, silanated, the Commission considers that the initial assessment made by the SCF should be reviewed as provided for in Article 11(5) of Regulation (EC) No 1935/2004.

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

In accordance with Article 29 (1)(a) of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the European Commission would like to ask the Authority to review the information provided by the company and advise on whether the new data raises issues regarding the safe use of the substance at the particle sizes reported.

ASSESSMENT

1. Background information provided

Silicon dioxide, silanated (FCM substance No 87, PM/REF 86285) was authorised in 1999 to be used as an additive for the manufacture of plastic food contact materials. The present document concludes on the safety of the substance based on information provided on the basic silica, the surface treated silica, and a study investigating the migration potential of the substance. Silica is an alternative name for silicon dioxide. These data have been supplied by EVONIK Industries AG.

According to the general information provided, synthetic amorphous silica prepared by a pyrogenic (fumed) process or by a precipitation process, is the starting material for silicon dioxide, silanated. For the pyrogenic process the size range of the primary particles of basic silica produced is typically in the region of 5 – 40 nm with the exact range depending on the process conditions used. For the precipitation process, the size range of the primary particles produced is typically in the region of 2 - 60 nm with the exact range depending on the conditions used.

For the silanated product, the surface modification can be performed with dichlorodimethylsilane but the use of other silanes is possible. The chemicals used for the surface modification are not the subject of this evaluation. Surface modification does not make a significant change to the size of the primary particles.

For both the basic (unmodified) silica and for the silanated silica, the information provided indicates that, although the SiO2 has a primary particle size of less than 100 nm, in the commercial products (the powder) the primary particles are aggregated and agglomerated.

2. Test data provided

In laboratory tests that were performed and submitted for this assessment, silicon dioxide, silanated, was examined for its physical form and for its potential to migrate from plastic food contact materials into food. Using TEM (transmission electron microscopy) analysis of the additive in powder form, the primary particles were estimated to be ca. 12 nm in size and they were all aggregated in the range 100-300 with some evidence of larger agglomerates. No isolated primary particles were observed in the many TEM images recorded and analysed. Using AF4-MALS (asymmetric-flow field flow fractionation with multi-angle light scattering detection) the particle size distribution of the powder product (dispersed in ethanol to allow injection onto the system) was estimated to be about 160 – 600 nm, peaking at about 300 nm. These estimates were slightly higher than the TEM results which could be caused by uncertainties in the radius calculation using the MALS. The overall conclusion, the presence of aggregates and the absence of detectable primary particles, is consistent between the two techniques used.

This substance was formulated into LDPE (low density polyethylene) at 0.5, 1 and 3 % w/w and the plastic was melt-extruded and blown into 60 µm thick films. TEM analysis of the LDPE films revealed that the size distribution of the substance in the plastic was not changed from that of the substance in powder form, with only aggregates larger than 100 nm and agglomerates seen and no isolated primary particles could be detected. The second sizing technique that was used for powder analysis, AF4-MALS, cannot be used for analysis of the substance in situ in plastics.

Migration testing of the film containing the highest level of 3 %, used the simulants 95 % ethanol, 3 % acetic acid and isooctane under a variety of time and temperature test conditions. The simulants were analysed using AF4-MALS. There was no detectable migration of the substance at the detection limit of the analytical method used, which was in the range of 0.3 to 0.6 µg/kg simulant.

Limited tests for the possible formation of reaction or breakdown products were conducted to compare substances extractable from a blank LDPE film with the extractables from the film made using 3 % w/w of the substance. No differences were detected using three methods, for volatile, semi-volatile and non-volatile substances.

3. Assessment

The Panel considered that the material used for the test was sufficiently representative of the substance listed as silicon dioxide, silanated, FCM substance 87. The substance is authorised for use as an additive in all types of plastics, without restriction, and it is considered that the polymer studied (LDPE) and the level of incorporation used (3 % (w/w) in the LDPE) are representative of other applications and there is no reason to believe that the findings would be significantly different if another polymer or another loading was used. Indeed in many aspects e.g. with respect to reactivity and migration potential, LDPE can be considered to be not simply representative but a worst-case polymer.

Transmission electron microscopy showed that the size distribution of the substance incorporated into LDPE was not changed by the plastic processing and that the substance remained in the form of aggregates larger than 100 nm. No isolated primary particles of smaller size could be detected. In well designed and conducted migration experiments including use of the swelling simulant isooctane, which interact strongly with LDPE, there was no detectable migration of the substance itself neither as primary nanoparticles nor as aggregates. Examination of the same migration simulants detected no formation of reaction or breakdown products from the substance itself or from any interaction between the substance and the LDPE matrix into which it was incorporated. Considering the chemical nature of silicon dioxide, silanated, which can be considered to be inert, the formation of reaction or breakdown products by a potential catalytic activity of the substance on polymers into which it is added, is not to be expected.

CONCLUSIONS

The panel considers that the material used for the test is sufficiently representative of the substance listed as silicon dioxide, silanated, FCM substance No 87. The substance is authorised for use as an additive in all types of plastics, without restriction, and it is considered that the polymer studied, LDPE, can be considered a worst-case polymer and the level of incorporation used (3 % w/w in the LDPE) is representative. The information provided demonstrates adequately the absence of isolated primary nanoparticles in the basic silicon dioxide and in the silanated silicon dioxide since only aggregates larger than 100nm along with larger agglomerates were observed using two independent measurement techniques, one of which was transmission electron microscopy (TEM). The particle size range was not affected when the silanated product was incorporated into a low density polyethylene film at 3 % w/w. Furthermore, there was no detectable migration of silicon dioxide of any particle size from this film into appropriate food simulants. Addressing the terms of reference provided by the Commission, at the particle sizes reported and based on the information provided that the situation described applies to all producers of synthetic amorphous silica, the substance silicon dioxide, silanated, does not raise a safety concern for the consumer in the currently authorised conditions of use.

DOCUMENTATION PROVIDED TO EFSA

1. Silicon dioxide, silanated. January 2014. Submitted on behalf of EVONIK

GLOSSARY

AF4-MALS	Asymmetric-Flow Field Flow Fractionation with Multi-Angle Light Scattering detection
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
FCM	Food Contact Material
LDPE	Low Density Polyethylene
SCF	Scientific Committee on Food
TEM	Transmission Electron Microscopy