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Safety assessment of the substance 'Tungsten Oxide' for use in food contact materials

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Abstract

This scientific opinion of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the risk assessment of the additive tungsten oxide, CAS No 39318-18-8 and FCM No 1064, for use in food contact materials as a reheat agent in polyethylene terephthalate (PET) at a maximum use level of 75 ppm (75 mg/kg PET). The substance is a mixture of tungsten oxides with tungsten at different oxidative levels. The average oxidation level of tungsten in the oxides is 2.86 corresponding to 19.93% oxygen content. Detailed information on impurities is provided as confidential. Specific migration from PET plaques with the substance at 150 mg/kg (double the maximum intended use level of 75 mg/kg) was determined into 95% ethanol, as a worst-case simulant for PET due to its swelling effect. Under these test conditions, the specific migration, measured as tungsten using ICP-MS, was at the level of 1 μg/kg. The Panel considered that due to the insolubility of the substance, this low migration will be typical for any foreseeable use as a reheat additive in PET. Two *in vitro* genotoxicity studies, a bacterial gene mutation test and an *in vitro* micronucleus assay, performed in accordance with the OECD Guidelines and in compliance with GLP, were provided by the applicant for the substance tungsten oxide and were considered negative by the CEF Panel. According to a scientific opinion on strategy for genotoxicity testing (EFSA, 2011), the three genotoxic endpoints, gene mutation, chromosomal and numerical aberrations, are covered by these two tests. The CEF Panel concluded that the substance tungsten oxide is not of safety concern for the consumer if the additive is used as a reheat agent in PET. For other technical functions or for use in other polymers, the migration should not exceed 50 μg/kg (expressed as tungsten).

Keywords: Tungsten oxide, CAS number 39318-18-8, FCM substance No 1064, food contact materials, safety assessment, evaluation

Requestor: Food Standard Agency, UK

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Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The purity of the substance has been provided under confidentiality and it is deleted awaiting the decision of the Commission

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list, EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004[1] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to European Food Safety Authority (EFSA) for their evaluation.

In this case, EFSA received an application from the Food Standard Agency, United Kingdom, requesting the evaluation of the substance tungsten oxide, with the CAS No 39318-18-8 and the FCM substance No 1064.

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 of the risks related to the intended use of the substance and to deliver a scientific opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of their application for the authorisation of tungsten oxide, to be used in FCM. Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Description of manufacturing process of substance/FCM
- Physical and chemical properties
- Intended use
- Existing authorisation(s)
- Migration of the substance

Toxicological data

- Bacterial gene mutation test
- Mammalian erythrocyte micronucleus test

2.2. Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently, there are three tiers with different thresholds triggering the need for more toxicological information as follows:

[1] 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 and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

According to the applicant, the substance tungsten oxide (blue oxide) is intended to be used as a reheat agent in polyethylene terephthalate (PET) material, at a maximum content of 75 mg/kg for contact with all types of foods at pasteurisation conditions and storage at room temperature for a long period.

The substance has not been evaluated by the SCF or EFSA in the past.

3.1. Non-toxicological data

The chemical formulae is WO_n (n = 2.72–2.9).

The substance is a mixture of tungsten oxides with tungsten at different oxidative levels. The average oxidation level of tungsten in the oxides is 2.86 corresponding to 19.93% oxygen content. The molecular weight of $WO_{2.72}$ is 227.36 and the molecular weight of $WO_{2.9}$ is 230.24. It is a powder with a particle size distribution in the range 0.25–20 μm and with a mean particle size of 5–20 μm. The purity of this tungsten oxide is [redacted]. Detailed information on impurities is provided as confidential. The substance is stable under the conditions of manufacturing of PET. It is essentially insoluble in water, acid and alcohols, but dissolves in aqueous alkali hydroxide solutions. The substance is neutral and chemical inert. Specific migration from PET plaques with the substance at 150 mg/kg (double the maximum intended use level of 75 mg/kg) was determined into 95% ethanol, as a worst-case simulant for PET due to its swelling effect. The test conditions were 10 days at 60°C, with measurements taken at 24 h, 5 days and 10 days. Under these conditions, the specific migration, measured as tungsten using inductively coupled plasma mass spectrometry (ICP-MS), was at the level of 1 μg/kg. The Panel considered that due to the insolubility of the substance, this low migration will be typical for any foreseeable use as a reheat additive in PET.

Such low migration levels (1 μg/kg) were also measured from low-density polyethylene (LDPE) plaques, determined under similar conditions, with the substance at 150 mg/kg and using 3% acetic acid and 95% ethanol.

3.2. Toxicological data

Two *in vitro* genotoxicity studies, appropriately performed in accordance with the OECD Guidelines and in compliance with good laboratory practice (GLP), were provided by the applicant for the substance tungsten oxide (CAS 39318-18-8). In a bacterial gene mutation test with the substance, no increase in revertants was induced in *Salmonella typhimurium* strains TA97A, TA98, TA100, TA102 and TA1535 tested up to 5,000 μg/plate with and without metabolic activation. Also in an *in vitro* micronucleus assay with human lymphocytes, no clastogenic/aneugenic effects were induced by the substance tested up to the limit of solubility and cytotoxicity (20 μg/mL (4 h ± S9 mix) and 40 μg/mL (24 h − S9 mix)). According to a scientific opinion on strategy for genotoxicity testing (EFSA, 2011), the three genotoxic endpoints gene mutation, chromosomal and numerical aberrations, are covered by these two tests. In conclusion, the Panel considers that the substance does not give rise to concern for genotoxicity.

According to the guidelines for FCM, these genotoxicity studies allow for a migration limit of 50 μg/kg.

Additional genotoxicity studies, as well as repeated-dose toxicity studies, were provided by the applicant for other tungsten compounds, such as tungsten trioxide and sodium tungstate dehydrate, but these were not needed, therefore were not used for this evaluation since the migration was anyway lower than 50 μg/kg.

The Panel noted that tungsten oxide was evaluated by the European Chemicals Authority (ECHA) and was assigned an oral derived no-effect level (DNEL) of 0.6 mg/kg body weight (bw) per day (ECHA, 2016).

4. Conclusions

The CEF Panel, having considered the above-mentioned data, concluded that the substance tungsten oxide is not of safety concern for the consumer if the additive is used as a reheat agent in PET. For other technical functions or for use in other polymers, the migration should not exceed 50 μg/kg (expressed as tungsten).

Documentation provided to EFSA

1) Initial dossier. October 2014. Submitted by ColorMatrix Group.
2) Additional data. March 2015. Submitted by ColorMatrix Group.
3) Additional data. August 2016. Submitted by ColorMatrix Group.

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European Commission, 2001. Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior its authorisation. Available online: http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf

Abbreviations

bw	body weight
CAS	Chemical Abstracts Service
CEF	Panel on food Contact Materials, Enzymes, Flavourings and Processing Aids
DNEL	derived no-effect level
ECHA	European Chemicals Authority
FCM	food contact materials
GLP	good laboratory practice
ICP-MS	inductively coupled plasma mass spectrometry
LDPE	low-density polyethylene
OECD	Organisation for Economic Co-operation and Development
PET	polyethylene terephthalate
SCF	Scientific Committee on Food