Scientific Opinion on the safety evaluation of the substance, 1,10-decanediamine, CAS No. 646-25-3, for use in food contact materials

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SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the substance, 1,10-decanediamine, CAS No. 646-25-3, for use in food contact materials

EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

European Food Safety Authority (EFSA), Parma, Italy

This scientific output replaces the earlier version published 21 February 2011

ABSTRACT

This scientific opinion of EFSA deals with the risk assessment of the monomer 1,10-decanediamine, CAS No. 646-25-3, REF. No. 15260 for which the CEF Panel concluded that there is no safety concern for the consumer if the substance is only used as a co-monomer for manufacturing polyamide articles for repeated uses in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to 150°C and its migration does not exceed 0.05 mg/kg food.

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KEY WORDS

1,10-Decanediamine; CAS number 646-25-3; Ref. No. 15260; Food contact materials; Safety assessment; Evaluation.

1 On request from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2009-00674, adopted on 4 February 2011.
2 Panel members: Arturo Anadón, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettel Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle. One member of the Panel, M.-L. Binderup declared an interest as she prepared the evaluation report of the substance under contract of her Institute DTU with EFSA. This was considered as a conflict of interest because she could not act at the same time as a representative of the contract or as a member of the Panel with voting rights. She was allowed to stay in the room to answer questions specifically addressed to her but did not participate in the discussion of the opinion. Correspondence: cef-unit@efsa.europa.eu
3 Acknowledgement: The Panel wishes to thank the members of the Working Group on Food Contact Materials for the preparation of this opinion: Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Roland Franz, Nathalie Gontard, Eugenia Lampi, Jean-Claude Lhuguenot, Maria Rosaria Milana, Karla Pfaff, Kettel Svensson and Detlef Wölfle for the support provided to this EFSA scientific output.
4 The changes do neither affect nor alter this scientific output. The adoption date has been updated.


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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 a competent Member State Authority for safety evaluation of a substance following a corresponding application from the industry.

The request received and the outcome of the safety evaluation is summarised below:

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested for evaluation of the substance 1,10-decanediamine with the CAS number 646-25-3 and the European Commission reference number (REF. No.) 15260, for use as a monomer in the production of polyamides at a maximum content of 55% (w/w). Finished articles are intended to come into contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to a few minutes at 150°C maximum. Finished articles will be used for repeated use applications and include parts in coffee machines or food contact surfaces of food processing equipments, such as injectors or filters. The dossier was submitted on behalf of EMS-Chemie AG.

The CEF Panel concluded that there is no safety concern for the consumer if the substance is only used as a co-monomer for manufacturing polyamide articles for repeated uses in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to 150°C and its migration does not exceed 0.05 mg/kg food.
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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.5

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 the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requesting the evaluation of the monomer, 1,10-decanediamine, with the CAS number 646-25-3 and the European Commission reference number (REF. No.) 15260.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;

2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 but need to be re-evaluated.

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ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, to evaluate the safety of the 1,10-decanediamine with a CAS number 646-25-3 and a REF. No. 15260. The request has been registered in the EFSA’s register of received questions under the number EFSA-Q-2009-00674. The dossier was submitted on behalf of EMS-Chemie AG.

Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a “SCF list” is retained for uniformity purposes. The definitions of the various SCF lists and the abbreviations used are given in the APPENDIX A.

2. General information

According to the applicant, the substance 1,10-decanediamine is intended to be used as a co-monomer in the production of polyamides. Maximum use is up to 55% (w/w). Finished articles are intended to come into contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to a few minutes at 150°C maximum. Finished articles will be used for repeated use applications and include parts in coffee machines or food contact surfaces of food processing equipments, such as injectors or filters.

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 intended use and existing authorisation
- Data on specific and overall migration
- Data on the identification and quantification of the oligomers
- Data on residual amount

Toxicity data:
- Bacteria gene mutation test
- In vitro mammalian cell gene mutation test
- In vitro mammalian chromosome aberration test
- In vivo micronucleus assay in mice
4. **Evaluation**

4.1. **Non-toxicological data**

Chemical formula: \( C_{10}H_{24}N_2 \)

Chemical structure: \[
\begin{array}{c}
\text{H}_2\text{N} \\
\text{NH}_2
\end{array}
\]

The substance has a molecular weight of 172.31 Da. It is moderately soluble in water and freely soluble in acidic media. It has a log octanol/water partition coefficient of 2.3.

Specific migration of 1,10-decanediamine was determined from polyamide with and without glass fiber reinforcement after contact for 4 hours at reflux temperatures with the food simulants water, 3% acetic acid and 50% ethanol. Taking into account the properties of the polymer and the solubility of the substance, 3% acetic acid is considered the most appropriate simulant. In addition, it should be noted that testing for 4 hours is largely exaggerated compared to the intended conditions of use. Because of the intended applications, a surface/mass ratio of 2 dm\(^2\)/kg food is also considered appropriate and therefore used for the determination of the migration instead of the default ratio of 6 dm\(^2\)/kg food.

The migration tests were carried out three times on the same test specimen in order to simulate the repeated use conditions. In the 3\(^{rd}\) test with 3% acetic acid, migration of the substance from the two polyamides was up to 2 µg/kg food simulant.

Overall migration tests were carried out in the repeated use test mode from the same polyamide samples into 3% acetic acid for 30 min at reflux temperature which is appropriate for the intended uses. In the 3\(^{rd}\) test, overall migration was below 1 mg/kg food simulant.

The five largest peaks of this overall migrate were identified with LC-MS analysis as oligomers, all containing the substance moiety. The highest migration was at 21 µg/kg for the oligomer with molecular weight of 548 Da. The four other identified oligomers and a few minor unidentified oligomers were estimated to migrate at or less than 10 µg/kg each.

4.2. **Toxicological data**

The substance 1,10-decanediamine was examined for its potential to induce reverse mutations in bacteria, forward mutations at the thymidine kinase (\( tk \)) locus in mouse lymphoma L5178Y cells, and structural chromosomal aberrations in Chinese Hamster V79 cells. The substance did not induce gene mutations in bacteria and mammalian cells either with or without metabolic activation. The test compound was clastogenic in mammalian with or without metabolic activation. In an in vivo micronucleus assay in mice 1,10-decanediamine was not toxic to the bone marrow, but there was indication of systemic availability due to toxicity observed in the highest dose group. In this study 1,10-decanediamine was not clastogenic/aneugenic. It is therefore concluded that 1,10-decanediamine is non-genotoxic in vivo.

Based on the lack of genotoxicity of the substance and that the other co-monomers are authorised aliphatic diamines and carboxylic acids, the low migration of the oligomers with a molecular weight below 1000 Da does not raise a safety concern.
CONCLUSIONS
The CEF Panel after having considered the above-mentioned data proposes that the substance 1,10-decanediamine be classified in the SCF_List 3, with the restriction of 0.05 mg/kg food and only to be used as a co-monomer for manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to 150°C.

DOCUMENTATION PROVIDED TO EFSA
Dossier referenced: n/a. Dated: August 2010. Submitted on behalf of EMS-Chemie AG.

REFERENCES
EC (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; http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf.
**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AFC</td>
<td>Scientific Panel on additives, flavourings, processing aids and materials in contact with food</td>
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<tr>
<td>bw</td>
<td>Body weight</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical abstracts service</td>
</tr>
<tr>
<td>CEF</td>
<td>Scientific Panel on food contact materials, enzymes, flavourings and processing aids</td>
</tr>
<tr>
<td>Da</td>
<td>Dalton</td>
</tr>
<tr>
<td>DSC</td>
<td>Differential Scanning Calorimetry</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EFSA</td>
<td>European food safety authority</td>
</tr>
<tr>
<td>FCM</td>
<td>Food Contact Material(s)</td>
</tr>
<tr>
<td>LDPE</td>
<td>Low density polyethylene</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No observed adverse effect level</td>
</tr>
<tr>
<td>PCE/NCE</td>
<td>Polychromatic erythrocyte/Normochromatic erythrocyte</td>
</tr>
<tr>
<td>Po/w</td>
<td>Octanol/water partition coefficient</td>
</tr>
<tr>
<td>REF No</td>
<td>Reference Number</td>
</tr>
<tr>
<td>SCF</td>
<td>Scientific Committee on food</td>
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<tr>
<td>w/w</td>
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