
TEST REPORT

N° FCM-22.168**REPORT DATE:** 17/01/2023**SUBJECT:** Determination of the overall and specific migration out of a 2 types of LDPE bags.**BY ORDER OF:** **Marisan NV**
Ambachtsweg 14
9820 Merelbeke
Belgium

The results of this report are exclusively related to the submitted and tested items as received.
IBE-BVI is not responsible for the information provided by the customer and doesn't guarantee the validity of the results in case of incorrect information that can affect the results.
Except in full version, this report shall not be reproduced without written approval of IBE-BVI.

Recognition:



Eng. Sara Geeroms
Head of Department
Food Contact Materials



Dr. Ann Delmotte
General Manager

1. Received sample

Sample receiving date: 02/11/2022

Description of the sample:

Sample A: LDPE bag 30µm
Article n°: 00442010

Sample B: LDPE grip seal bag 50 µm
Article n°: 00443172

Application: contact with all kinds of foods.

This information was provided by 'Marisan'.

Contact person: Jos van Rijn
E-mail contact person: jos@marisan.be

The sampling was performed by 'Marisan'.

2. Executed tests

Analysis period: 09/11/2022 – 09/01/2023

The legislations and standards mentioned below are all referring to their last published version at the time of testing.

a. Determination of the overall migration

These tests are executed under the Belac accreditation.

All plastic materials intended to come into contact with food have to be tested on their migration behaviour, in accordance with the European Regulation No 1935/2004 (and amendments) and the European Regulation No 10/2011 (and amendments).

Regulated by the above-mentioned legislations the overall migration limit is 10 mg/dm².

In conformity with the European Regulation No 10/2011 and amendments the simulants and test conditions presented in table 1 were selected.

Table 1: selected simulants and test conditions

| Simulant | Contact conditions |
|----------------------------------|---------------------------|
| Simulant A: ethanol 10% (v/v) | 10 days at 40°C (OM2) |
| Simulant B: acetic acid 3% (m/v) | |
| Simulant D2: olive oil | |

The test method was based on EN 1186-1, EN 1186-4 and EN 1186-5.

| | |
|---|----------------------|
| Exposed contact surface into simulants A and B: | 94.8 cm ² |
| Used volume simulants A and B: | 100.0 ml |
| Contact method simulants A and B: | migration cell |
| Exposed contact surface into simulant D2: | 94.8 cm ² |
| Used volume simulant D2: | 100.0 ml |
| Contact method simulant D2: | migration cell |

After the contact period, simulants A and B were evaporated and the residual weights were determined. To determine the migration result into simulant D2, the olive oil was extracted out of the test specimens, trans-esterified and analysed chromatographically. The obtained amount of olive oil was subtracted from the total weight loss of the test specimens.

b. Determination of the specific migration¹

Regulated by the European Regulation N° 10/2011 and amendments, the specific migration of several components is restricted by their Specific Migration Limit (SML).

The specific migration of the substances presented in table 3 was determined. The specific migration limits are laid down in the European Regulation No 10/2011 and amendments. The specific migration of the listed substances is measured in their respective worst-case simulant.

In conformity with the European Regulation No 10/2011 and amendments the following test conditions, as displayed in table 2 were selected.

Table 2: selected simulants and test conditions

| simulant | Contact condition |
|----------------------------------|--------------------------|
| Simulant B: acetic acid 3% (m/v) | 10 days at 60°C |
| Simulant D2: olive oil | 10 days at 60°C |

Table 3: determination of the specific migration - substances

| Substance | CAS number | simulant | SML (mg/kg) |
|--|-------------------|-----------------|--------------------|
| Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (<i>Irganox 1076</i>) | 2082-79-3 | Simulant D2 | 6 |
| Primary Aromatic Amines (PAA) – listed as CMR (*) | - | Simulant B | 0.002 |
| Primary Aromatic Amines (PAA) – not listed as CMR Cat 1 A/B | | Simulant B | T = 0.01 |

(*) Primary aromatic amines listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 and for which no migration limit is specified in table 1 of Annex I of Regulation EU n° 10/2011 and amendments.

The test method was based on EN 13130-1.

Exposed contact surface: 100 cm²
Used volume simulant: 100 ml
Contact method: immersion

¹ This test is outsourced to an IBE-BVI approved laboratory.

3. Results

a. Determination of the overall migration

The results of simulants A and B are mean values of two measurements, the results of simulant D2 are mean values of four measurements. No reduction factor was used for simulant D2.

All results are expressed in mg/dm² and are presented in table 4.
The overall migration limit is 10 mg/dm².

Table 4: results for the overall migration analyses

| Simulant | Result sample A (mg/dm²) | Result sample B (mg/dm²) |
|----------------------------------|--|--|
| Simulant A: ethanol 10% (v/v) | < 0.5 | < 0.5 |
| Simulant B: acetic acid 3% (m/v) | < 0.5 | 0.7 |
| Simulant D2: olive oil | < 3.0 | < 3.0 |

Additionally, it is confirmed that no visual discolouration of the simulants after the contact period was observed.

b. Determination of the specific migration

The results, presented in table 5 up to table 7, are mean values of three measurements and are expressed in mg/kg foodstuffs.

Table 5: results for the specific migration analysis of CMR Primary Aromatic Amines

| Substance name | CAS n° | Results sample A (mg/kg) | Results sample B (mg/kg) | SML (mg/kg) |
|-------------------------------------|---------------|---|---|------------------------|
| 4-aminoazobenzene | 60-09-3 | < 0.002 | < 0.002 | 0.002 |
| 4-aminobiphenyl | 92-67-1 | < 0.002 | < 0.002 | 0.002 |
| Benzidine | 92-87-5 | < 0.002 | < 0.002 | 0.002 |
| 4-chloro-o-toluidine | 95-69-2 | < 0.002 | < 0.002 | 0.002 |
| 2-Naphthylamine | 91-59-8 | < 0.002 | < 0.002 | 0.002 |
| 2,4-diamino-anisol | 615-05-4 | < 0.002 | < 0.002 | 0.002 |
| 4,4-Methylenbis-2-chloraniline | 101-77-9 | < 0.002 | < 0.002 | 0.002 |
| 3,3-Dichlorobenzidine | 91-94-1 | < 0.002 | < 0.002 | 0.002 |
| 3,3-Dimethylbenzidine | 119-90-4 | < 0.002 | < 0.002 | 0.002 |
| 3,3-Dimethyl-4,4-diaminodiphenylmet | 119-93-7 | < 0.002 | < 0.002 | 0.002 |
| 4,4-Diaminodiphenylmethane | 838-88-0 | < 0.002 | < 0.002 | 0.002 |
| p-Cresidine | 120-71-8 | < 0.002 | < 0.002 | 0.002 |
| 4,4'-Methylene bis(2-chloroaniline) | 101-14-4 | < 0.002 | < 0.002 | 0.002 |
| 4,4'-oxydianiline | 101-80-4 | < 0.002 | < 0.002 | 0.002 |
| 4,4-Thiodianiline | 139-65-1 | < 0.002 | < 0.002 | 0.002 |
| 2-Aminotoluene | 95-53-4 | < 0.002 | < 0.002 | 0.002 |
| 2,4-Diaminotoluene | 95-80-7 | < 0.002 | < 0.002 | 0.002 |
| 2-Methoxyaniline | 90-04-0 | < 0.002 | < 0.002 | 0.002 |
| 2,4,5-trimethylaniline | 137-17-7 | < 0.002 | < 0.002 | 0.002 |
| 2-Amino-4-nitrotoluene | 99-55-8 | < 0.002 | < 0.002 | 0.002 |

Table 6: results for the specific migration analysis of non-CMR Primary Aromatic Amines

| Substance name | CAS n° | Results sample A (mg/kg) | Results sample B (mg/kg) | SML (mg/kg) |
|--------------------------------------|---------------|---------------------------------|---------------------------------|--------------------|
| 4-Aminotoluol | 106-49-0 | < 0.01 | < 0.01 | 0.01 |
| 3-Amino-4-methoxybenzanilide | 120-35-4 | < 0.01 | < 0.01 | 0.01 |
| 2-Methoxy-4-nitroaniline | 94-70-2 | < 0.01 | < 0.01 | 0.01 |
| 5-Chloro-2-methylaniline | 95-79-4 | < 0.01 | < 0.01 | 0.01 |
| 2-methoxy-4-nitroaniline | 97-52-9 | < 0.01 | < 0.01 | 0.01 |
| 2,4-Dinitroaniline | 97-02-9 | < 0.01 | < 0.01 | 0.01 |
| 4-chloro-2,5-dimethoxyaniline | 6358-64-1 | < 0.01 | < 0.01 | 0.01 |
| 4-Aminobenzamide | 2835-68-9 | < 0.01 | < 0.01 | 0.01 |
| 2,5-Dichloroaniline | 95-82-9 | < 0.01 | < 0.01 | 0.01 |
| Aniline | 62-53-3 | < 0.01 | < 0.01 | 0.01 |
| 2,4-Dimethylaniline | 95-68-1 | < 0.01 | < 0.01 | 0.01 |
| 2,2'-(Ethylenedioxy)dianiline | 52411-34-4 | < 0.01 | < 0.01 | 0.01 |
| 1-Naphthylamine | 134-32-7 | < 0.01 | < 0.01 | 0.01 |
| 2-Methoxy-5-nitroaniline | 99-59-2 | < 0.01 | < 0.01 | 0.01 |
| 2,4,5-Trichloroaniline | 636-30-6 | < 0.01 | < 0.01 | 0.01 |
| 4-Nitro-1,2-phenylenediamine | 99-56-9 | < 0.01 | < 0.01 | 0.01 |
| 2-amino-5-methylbenzenesulfonic acid | 88-44-8 | < 0.01 | < 0.01 | 0.01 |
| 2,6-Dimethylaniline (2,6-Xylidine) | 87-62-7 | < 0.01 | < 0.01 | 0.01 |
| 3-Amino-1-nitrobenzene | 99-09-2 | < 0.01 | < 0.01 | 0.01 |
| Sum of CAS n°. 88-51-7 and 88-53-9 | 88-44-8 | < 0.01 | < 0.01 | 0.01 |

Table 7: results for the specific migration analysis of intentionally added substances

| Substance name | CAS n° | Result sample A (mg/kg) | Result sample B (mg/kg) | SML (mg/kg) |
|---|---------------|--------------------------------|--------------------------------|--------------------|
| Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (Irganox 1076) | 2082-79-3 | < 3 | < 3 | 6 |

4. Conclusion

The results presented in table 4 give evidence that the overall migration of the tested samples is less than the maximum limit of 10 mg/dm² for simulant A (ethanol 10%, representing aqueous foods), simulant B (acetic acid 3%, representing foods which have a pH below 4,5) and simulant D2 (olive oil, representing foods which contain free fats at the surface) using the given conditions.

In accordance with the European Regulation No 10/2011 and amendments, the use of simulants A, B and D2 covers all kinds of foods.

The used test condition (OM2) represents any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70^{\circ}\text{C} \leq T \leq 100^{\circ}\text{C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.

The results presented in table 5 to table 7 give evidence that, for both samples, the specific migration of the mentioned components do not exceed their specific migration limits as laid down in the European Regulation No 10/2011 and amendments under the given conditions.

The obtained results and findings are inextricably related to the materials as submitted and examined. Any change in material composition is not covered by the performed analyses.



Eng. Sara Geeroms
Head of Department
Food Contact Materials

Annex: sample pictures



Sample A



Sample B