

RT FC240078.01 Rev.0

Referred to the Samples: FC240764.01, FC240764.02, FC240764.03, FC240764.04

EURAL GNUTTI SPA

Via S. Andrea, 3
Rovato
BS

Pistoia, 30/08/2024

OBJECT: Evaluation test of bismuth transfer from aluminium alloy (Bi <1% by weight)



Figure 1: Aluminum alloy - EN-AW 6026 LF

Food Contact Center s.r.l.

Serravalle Pistoiese Tel: +39 0573 245244

Brescia Tel +39 030 3457131

Cuneo Tel. +39 375 5082854

info@FoodContactCenter.com

www.FoodContactCenter.com

P.IVA: 01898850472

C.F.: 01898850472

Headquarter: Via del Redolone 65, 51034, Serravalle Pistoiese

R&D Pilot Plant: Via Enrico Pestalozzi 63, 51100 Pistoia

Laboratory: Via Aldo Moro 16, 25124 Brescia

Sales Office: Via Roma 64, 12100 Cuneo

Registered and Administrative

Office: Via Vecchia Provinciale Lucchesa 19e

Fraz. Stazione Masotti 51030
Serravalle Pistoiese

1. Introduction

The client intends to carry out an evaluation study of the transfer of bismuth from aluminium alloy (Bi <1% by weight) with which it produces semi-finished products also intended for the food contact market.

The laboratory, after appropriate validation of the method, carried out the transfers in various food simulants and under various contact conditions in order to have a detailed study of the material's behavior.

2. Tests performed

2.1 Determination of Bismuth after a contact of 10 days at 60°C - sample FC240764.01

In order to simulate the worst conditions of prolonged use provided for by Regulation 10/2011, it was performed the migration of bismuth after 10 days at 60°C in 3% acetic acid.

It was also performed the migration of bismuth in simulants water, 10% ethanol and oil.

Parameter	Result mg/kg food	Lim. Quantification mg/kg food
Bismuth release in acetic acid 3%	0,4	0,1
Bismuth release in water	<LoQ	0,1
Bismuth release in ethanol 10%	<LoQ	0,1
Bismuth release in oil	<LoQ	0,1

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AcOH 3%

Water

EtOH 10%



Figure 2: Specimens after contact of 10 days at 60°C in Acetic Acid 3%, Water, Ethanol 10%

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Figure 3: Specimens after contact of 10 days at 60°C in oil

Following the contact with 3% acetic acid for 10 days at 60°C, it is observed a change in the specimen and also a clouding after the contact with water and 10% ethanol.

No changes are observed after the contact with oil.

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2.2 Determination of Bismuth after a contact of 4h at 100°C - sample FC240764.02

The analysis was carried out following a 4-hour contact at 100°C in aqueous simulants, Acetic 3% equivalent to a 1-hour contact at cooking temperatures.

The contact was performed by putting 82.9 cm² of the sample in contact with 138 mL of simulant, S/V=0.6 ratio.

Parameter	Result mg/kg food	Lim. Quantification mg/kg food
Bismuth release in acetic acid 3%	0,2	0,1
Bismuth release in water	<LoQ	0,1
Bismuth release in ethanol 10%	<LoQ	0,1



Figure 4: Specimens after a contact of 4 hours at 100°C in Acetic 3%, Water, Ethanol 10%

Following the contacts with Acetic 3%, Water, Ethanol 10% for 4 hours at 100°C, it is observed a slight clouding.

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2.3 Determination of Bismuth after a contact of 1h at 175°C - sample FC240764.03

The analysis was conducted after a 1-hour contact at 175°C with oil simulant. The determination of bismuth in oil was performed after an acid mineralization process and subsequent analysis in ICP-MS.

Parameter	Result mg/kg food	Lim. Quantification mg/kg food
Bismuth release in oil	<LoQ	0,1



Figure 5: Samples after a contact of 1 hour at 175°C in simulant oil

No alterations are observed after the contact with oil 1 hour at 175°C.

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2.4 Determination of Bismuth after a contact of 1h at 200°C - sample FC240764.04

For temperatures above 175°C, the simulant E (Tenax, as required by Regulation 10/2011) was used as a substitute for oil for the analysis of the migration of bismuth in MPPO. The determination of bismuth in MPPO was performed after an acid extraction process and subsequent analysis in ICP-MS.

Parameter	Result mg/kg food	Lim. Quantification mg/kg food
Bismuth release in MPPO	<LoQ	0,1

No changes are observed after the contact with simulant MPPO of 1 hour at 200°C.

3. Conclusions

According to the report "Toxicological evaluation and Tolerable Daily Intake derivation of Bismuth" and based on the available toxicological data, bismuth is not mutagenic, carcinogenic, nor toxic to reproduction. Several studies indicate that insoluble bismuth compounds exhibit low toxicity, while soluble organic compounds, such as bismuth citrate, exhibit higher toxicity. This toxicity increase is probably due to the increased absorption of soluble salts of bismuth in the human body after ingestion.

The oral Tolerable Daily Intake (sTDI) was calculated using the most reliable and conservative toxicological data in the SCCS opinion for bismuth citrate, a water-soluble bismuth salt.

The sTDI is set at 0.08 mg/kg body weight per day. This value was determined according to the FCA 2020 guidelines and corresponds to an oral intake level of 4.8 mg per person per day, for an adult of 60 kg body weight, thus corresponding to a specific migration with a value of 4.8 mg/kg food.

The migration values, which were found in the migration tests performed, are always lower than the specific migration limit calculated from the SDI, therefore, based on the analyses carried out, there are no critical issues related to the transfer of Bismuth.

The Technical Management
Marinella Vitulli



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