

TO: **SANMER S.A.**  
N/Ref:1941

2<sup>nd</sup> June of 2021

## **DECLARATION OF COMPLIANCE WITH FOOD CONTACT LEGISLATION**

The food metallic cans and ends with the following structure, depending on the format and/or element:

- External coating (printed or not) or without coating.
- Metallic substrate (functional barrier) ECCS and/or ETP.
- Internal coating, with sealing synthetic compound.

Manufactured by DOMIBERIA S.L.U. to **Sanmer**, which are destined to be in direct contact with wet, aqueous, acid and fatty foods, used under the conditions of pasteurization or sterilization process up to 1h 121°C and long storage at ambient temperature<sup>1</sup> comply with the appropriate current EU and US legislation<sup>2</sup>, as:

- **EU Regulation (EC) Nº 1935/2004** regarding materials intended to come into contact with foodstuffs
- **EU Regulation (EC) Nº 2023/2006** regarding Good Manufacturing Practices for materials and articles intended to come into contact with food.
- **EU Regulation (EC) Nº 1895/05** regarding the use of certain epoxy compounds in materials in contact with foodstuffs.
- Although specifically does not relate to coated metal packaging, **our internal coatings and sealant compound** comply with the **EU Regulation Nº 10/2011** related to plastics in contact with food.

**Compliant with restrictions:** the compliance with global and specific migrations, according to FDA and EU protocols have been checked and confirmed by external laboratories. According to the section 3 Annex III of Regulation (EC) No 10/2011, the overall migration into simulants has been determined based on a surface area to volume ratio of 6dm<sup>2</sup>/kg. The tests reports confirm compliance with the overall migration requirements specified (OML 10 mg/dm<sup>2</sup>), **and the specific migrations including the new limit for BPA of 0,05 mg/kg stated in the EU Regulation Nº 2018/213.**

- Overall migration<sup>3</sup>: was determined as dry residues of migrates. The organic components of the dry residue were determined
- Specific migrations: according to FDA and EU protocols have been checked at external laboratories. The test reports confirm compliance with the necessary specific migration requirements.

Reports of migrates of substances with a restriction is considered supporting documentation and it is available to the competitive authorities on demand. It is considered confidential information so cannot be given to third parties.

	Global migration (mg/dm <sup>2</sup> )		
	Sim A - 10% ethanol (1h 121°C + 10d 40°C)	Sim B - 3% acetic acid (1h 121°C + 10d 40°C)	Sim D2 - Oil or equivalent (1h 121°C + 10d 40°C)
3PC	<4.5	<5.3	<2.0
NEO	<4.5	<5.3	<7.1
EOE	<3.6	<3.7	<7.8

These data have been also checked by calculation in the worst size can case for the lacquers used in this format and compliance have been verified also for it.

- In addition, when the articles are denominated **BPA NI**, they comply with the **French regulation 2012-1442**, so Bisphenol A has not been used as ingredient in the formulation of the internal coatings used
- Where relevant, **EU Directive 78/142/EEC** relating to materials and articles which contain vinyl chloride monomer and which are intended to come in to contact with food.
- Tinplate and ECCS used comply with **EN 10333 y EN 10335** respectively
- Aluminum used complies with **EN 602:2004 y EN 541:2007**.
- With respect to contamination of food specially by the packaging and when packed and processed in accordance with recognized good canning practice<sup>4</sup>, **EU Regulation (EC) Nº 1881/2006** setting (*inter alia*) maximum levels of inorganic tin, lead, cadmium and mercury in foodstuffs.
- All internal lacquers are formulated in compliance with Council of Europe **Resolution AP(2004)1 y la CEPE European Coatings Code of Practice**
- All inks and external coatings comply with the **EuPIA/CEPE** guidelines.

Furthermore, the internal coatings and sealants are formulated under the US FDA CFR21 175.300 guidelines for food/beverage category and conditions of use for which they are sold and satisfy the migration requirements. They also comply with the Swiss legislation related to BADGE and derivatives.

This Document is valid for 5 years after the date of creation. Will be replaced only if there are relevant changes in the legislation or process that can affect it.

Sincerely,

Darío Villamarín

Resp. Calidad Domiberia



<sup>1</sup>25°C is considered ambient temperature. Filler has to keep in mind that at higher temperature the aging process could be accelerated. Is the responsibility of the filler and final seller to keep good storage conditions. It is also recommended to store the articles far from direct natural light and under no humidity atmosphere conditions.

<sup>2</sup> This document is applicable in EU, USA and the territories that accept EU and US regulatory compliance. If the products are going to be used out of this coverage territories, please contact Domiberia.

<sup>3</sup>Conformity with overall or specific migration is based on the use of recognized simulants. Actual migration levels are dependent on the composition of the food product, the method of processing the food in contact with the article, and the storage conditions in which it is held. It is the packer's responsibility to ensure in the case of any individual food product that migration levels remain within permitted limits, following the good manufacturing practices, since Domiberia S.L.U. has no control over the actual conditions of use, or of the composition, processing and storage conditions of the final product.

<sup>4</sup>Maintaining compliance with the limits for metals including tin in food in Regulation (EC) N 1881/2006 is the responsibility of the filler as the key factors determining metal release (headspace control, food product purity control, surface area to volume ratio, processing and storage conditions and setting of appropriate shelf-life) are specifically within the filler's control. Food canning practice is the responsibility of the filler and involves proactive assurance by the filler that the can/end specification is suitable for the specific foodstuffs under the conditions of filling, storage and distribution, and that an appropriate shelf life has been set taking account of the actual foodstuff packed