

Certificate Quality Department

SB - DECLARATION OF COMPLIANCE TO REGULATIONS ON MATERIALS INTENDED TO COME INTO CONTACT WITH FOOD as per Article 16 of REGULATION (EC) N° 1935/2004

Trelleborg Izarra, S.A.U. hereby certifies our compliance with materials and articles intended to come into contact with food, as per article 16 of REGULATION (EC) N° 1935/2004.

We hereby declare that the materials intended to come into contact with food entering into the composition of our products under reference Blue **SB (SAPPHIRESIL - S6A301 - Blue silicone sheet)** belong to the category of materials RUBBER (as per Annex I of regulation EC 1935/2004).

We declare that our products comply with the requirements of:

- REGULATION (EC) N° 1935/2004, dated 27/10/2004
- REGULATION (EC) N° 2023/2006., dated 22/12/2006

This declaration is based on test references E18-42690, carried out on 04/01/2019, in an external Laboratory according to specifications of article 6 of "Arrêté du 25 Novembre 1992" of France:

Extraction test condition according to French norm.

Simulants	Simulant Media	Time Temperature	Migration of substances	Limit	Units
D1	50% Ethanol	3x2 hours, 70°C	Overall migration	≤ 10	mg/dm ²
B	3% Acetic Acid	3x2 hours, 70°C	Overall migration	≤ 10	mg/dm ²
			Tin – (Sn)	≤ 0,1	mg/kg

Material content	Time Temperature	Migration of substances	Limit	Units
Free volatil organic substance	4 hours, 200°C	Average FVOS	≤ 0,5	%
Residual peroxides	/	Peroxides	≤ 0,08	%

Additionally, Blue SB (S6A301 is in compliance with FDA 21 CFR Part 177.2600 according to migration analysis, using as simulants Distilled Water for Aqueous. Test Reference is E18-42691 carried out on 04/01/2019, in an external Laboratory.

Extraction test condition CFR 21&177.2600 – USA.

Test	Limit (mg/in ²)
Extraction in distilled water 7 hours	≤ 20
Extraction in distilled water 2 hours	≤ 1

For information, we confirm furthermore that these materials contain no phthalate and no bisphenol A.



María Gutiérrez-Cortines
Izarra, 16/06//20
Quality Department