Food-contact declaration of conformity - Bluecare & Detect - EU & FDA

Manufacturer (Business operator - annex IV EU n°10/2011))	**FABULOUS S.A.S** Olivier Coulet - CTO contact@fabulous.com.co 2 avenue Roger Salengro 69120 Vaulx-en-Velin FRANCE
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Date of Declaration	28.01.2025 revised version n°1.3
Products identity	**BLUECARE,** PA11 Safety Blue in Mass with optical Detection **DETECT,** PA11 Composite Navy Blue in Mass with Metal & optical Détections

European Union (EU)

Confirmation of compliance

The plastic materials BLUECARE and DETECT meet the relevant requirements laid down in the following regulations :

➔ **Regulation (EC) N° 1935/2004 of the European Parliament and of the Council of 27 October 2004 (and its amendments) on materials and articles intended to come into contact with food.**

➔ **Commission Regulation (EU) N° 10/2011 of 14 January 2011 (and its amendments) on plastic materials and articles intended to come into contact with food.**

Substances used

The specific restrictions mentioned in Commission regulation (EU) N° 10/2011, most recently amended by Commission Regulation (EU) 2020/1245 of 2 September 2020, have to be ensured. Compliant tests have been investigated and passed by the manufacturer under the control of an European certified laboratory (listed by EFSA), regarding overall migrations (OML) and specific migrations (SML). Manufacturer provides below adequate information relative to the substances used for which restrictions and/or specifications are set out in annex I and II to the Regulation, to allow the downstream business operators to ensure its own compliance with the Regulation.

Substances *Conform to MSDS informations rules on ingredients (see chapter 3 - MSDS)*	**SML investigated & passed**
CAS n°2432-99-7	5 mg/kg
CAS n°1332-37-2	N/A
CAS n°1345-16-0	List annex II table 1

Specifications on the use of the materials

The materials are in compliance with the overall migrations limits (OML: limit 10 mg/d2) and specific migrations limits (SML):

- ➔ All foods, including alcoholic drinks.
- ➔ Any long term storage at room temperature or below, including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes.
- ➔ Repeated short-term contact at room temperature.

The test conditions used were 10 days at 40°C and 10 days at 60°C (OM2 for the metals & metalloids test in stimulants).

Good Manufacturing Practices (GMP)

The products BLUECARE & DETECT comply with the GMP requirements laid down in Regulation (EU) N° 2023/2006 on the Good Manufacturing Practices applicable to materials and articles intended to come into contact with foodstuffs.

United States of America (USA)

Confirmation of compliance

Manufacturer confirms that these products fulfill the requirements on materials used for articles or components of articles intended to come into contact with food as described in **Code of Federal Regulations (CFR) title 21 - Chapter 1 - Subchapter B of the Food and Drugs Administration (FDA)** in the following sections:

- ➔ **§174 -** *Indirect food additives - General -*
  - ◆ § 174.5 General provisions applicable to indirect food additives (including Good Manufacturing practices).
  - ◆ § 174.6 Threshold of regulation for substances used in food-contact articles.
- ➔ **§175.300 - Resinous and Polymeric Coatings** - *Indirect food additives - adhesives and components of coatings.*
- ➔ **§177.1500 - Nylon resins** - *Indirect food additives - Polymers*
  - ◆ §177.1500 - Nylon 11 resine (category 5.1)
    - Nylon 11 resins for use in articles intended for 1-time use or repeated use in contact with food .
  - ◆ §177.1500 - Nylon 11 resine (category 5.2) (a,b)
    - Nylon 11 resins for use only:
      - (a) In articles intended for repeated use in contact with food.
      - (b) In side-seam cements for articles intended for 1-time use in contact with food and which are in compliance with § 175.300 of this chapter .
- ➔ **§178.2010 Antioxidants and/or stabilizers for polymers** - *Indirect food additives: adjuvants, production aids, and sanitizers.*
- ➔ **§178.3297 Colorants for polymers** - *Indirect food additives: adjuvants, production aids, and sanitizers.*

Specifications on the use of the materials

BLUECARE and DETECT materials have been studied and approved by the manufacturer under the control of a certified laboratory to issue an FDA compliance rating. Materials comply with the following global migrations (OML):

- No restriction for plastic intended to come into contact with non-alcoholic foods.
- Restriction for alcoholic drinks.

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General Notice:

There are restrictions in each of the regulations that must be taken into account by using BlueCare or Detect. Users must review all applicable regulations and restrictions to assure compliance. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be ensured in each case by the downstream business operator who places any finished food contact article on the market.

M. Olivier Coulet
Chief Technical Officer (CTO)

FABULOUS
INNOVATIVE MATERIALS + 3D APPLICATIONS
FABULOUS SARL . contact@fabulous.com.co
TVA FR00 799529383 ; SIRET 799529838 00017
Siège Social : 55 Quai St Vincent 69001 LYON
MATERIALS APPLICATIONS