PRODUCT DOSSIER

TBF 300 – BIOFILM DETECTION TEST

Betelgeux

Contents

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1. Product description

The **TBF 300** BIOFILM DETECTION TEST is a rapid test kit for detection of biofilms on surfaces, manufactured and commercialized by **Betelgeux, S.L.**

TBF 300 is an innovative tool for microbiological controlling contamination in the form of biofilms in industries and public facilities, and it is an effective alternative to methods currently used for control of microbiological contamination.

This product results from several years of research in collaboration with Universidad Complutense de Madrid (Spain), within a project partially funded by Centro para el Desarrollo Tecnológico Industrial (CDTI).

2. Functions and features

TBF 300 is a product for **rapid detection of biofilms** on surfaces. Using this product detection of biofilms is:

- **Fast:** the results obtained in minutes.
- **Easy:** the detection is achieved by visual inspection, no specialized personnel or complex equipment are required.
- **Selective:** the product reacts with the exopolymeric matrix of biofilms. The positives signals appear only when biofilms are present.
- **Economic:** the cost per sample is lower than other hygiene control methodologies such as ATP-luminiscence monitoring and collection of microorganism with culture plates.

The mechanism of action of the **TBF 300** BIOFILM DETECTION TEST is based on dyes that are specific of the exopolymeric matrix of the biofilm where microorganisms are embedded. The dye attaches irreversibly to components of the biofilm matrix and enables its detection by visual inspection.

The product is applied as foam, allowing its use on horizontal and inclined surfaces. The foam adhered to the surface during the recommended application time, ensuring the biofilm is adequately dyed. The foam applied shows a strong fuchsia colour and it is readily dissolved in water. Permanent coloration signals the presence of a biofilm on the surface.

3. Presentation format

The **TBF 300** BIOFILM DETECTION TEST is commercialized in a spray can format; with a volume of 150 mL capacity. This format enables easy handling and storage of the product as it is ready to use.

The product is commercialized in boxes containing 3 units. Each bottle is presented in an individual package that contains:

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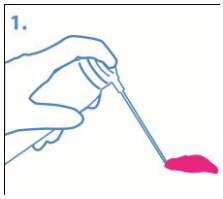
- A **TBF 300** bottle.
- An extension tube for easier foam application.
- Instructions in English and Spanish.

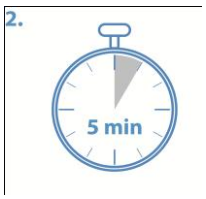
Each bottle of **TBF 300** allows sampling approximately 300 points according to the sampling guidelines described in this dossier.

4. Instructions for use

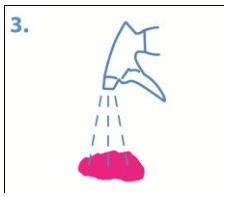
Identification of biofilm growth spots can be achieved using **TBF 300** through the following steps:



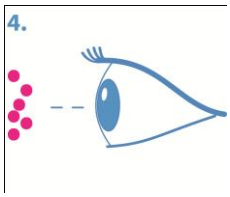
Select the surface to be examined and apply **TBF 300** foam over an area of approximately 10 cm^2.



Allow the product to act for at least 5 minutes.



Rinse the sampled area with water to remove the foam.



Check whether, after rinsing, fuchsia coloration remains, indicating the presence of biofilms.

It is advised to employ the **TBF 300** BIOFILM DETECTION TEST for evaluating hygienic conditions of surfaces after cleaning and disinfection operations. The product should be applied on a set of sampling points across the surface to test whether biofilms are present. These surfaces should be thoroughly rinsed after the test is performed to remove residues that could contact foods or other sensitive products.

TBF 300 must not be applied on foods or sensitive products.

PRECAUTIONS FOR USE

The product contains a strong dyeing agent. It should be applied in small doses in a controlled manner, using gloves to prevent dyeing the skin.

Do not apply **TBF 300** on porous surfaces that can retain the dyeing agent permanently (wood, fabric, paper, etc.). If not sure, apply a small amount of foam on a test sample of the surface to check compatibility.

Rinse waters can contain a high amount of dyeing agent that can soil absorbing materials in the rinse path.

In case of needing to remove the colour from rinse waters, a diluted solution of nitric acid (1 % w/w) can be applied.

5. Composition and classification

The **TBF 300** BIOFILM DETECTION TEST contains:

<1% Dye (fluorine)

2,5-10% Anionic surfactants for foam production

2,5-10% Non-ionic surfactants for foam production

2,5-10% Propellant organic gas to produce an aerosol.

5.1. Hazard classification

The product is classified as EXTREMELLY FLAMMABLE (F+) due to containing a small amount of flammable gases used as propellant. The composition in a liquid format, excluding the propellant, is classified as not dangerous.

This classification is based on Directive 67/548/CE and Directive 1999/45/CE, adapted to Regulation (CE) 1907/2006 (REACH).

Detailed information about hazards, toxicity and storage and transport guidelines can be found in the Material Safety Data Sheet in Annex I.

5.2. Material compatibility

The product is not corrosive and do not react with non-porous materials such as stainless steel, aluminium, cooper, Teflon... On porous and absorbent material permanent dyeing of the material can occur.

6. Examples of application in industry

Examples of application of **TBF 300** to monitor hygienic conditions in food industries are described below.

The essays were performed after cleaning and disinfection operations, testing various sampling points where biofilm growth could occur.

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6.1. Poultry industry

Several surfaces of a poultry slaughterhouse where tested for biofilm presence after cleaning and disinfection operations. Testing was performed following the recommendation protocol: the product was applied on selected sampling spots, surfaces were rinsed after a few minutes and they were checked to identify permanent coloration.

The following pictures show various examples about **TBF 300** application:

Figure 1. TBF 300 was applied on a poultry hanger after cleaning and disinfection (left). After rinsing, residual coloration was observed, indicating presence of biofilms (centre). The hanger was subsequently cleaned and disinfected using biofilm-removal detergents and the **TBF 300** test was performed again. After rinsing, surfaces were clear of dye, indicating the biofilms were removed (right).

Figure 2. TBF 300 foam applied on a hard to reach spot for cleaning operations. After rinsing a strong presence of biofilms is detected.

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Figure 3. Biofilms presence of transport equipment which has not been properly cleaned.

Figure 4. TBF 300 foam applied on a slicer that is frequently cleaned and disinfected by hand. No biofilms were detected. This result is consistent with low values of ATP luminescence detected and absence of microbiological contamination.

6.2. Fish industry

A similar testing procedure was performed at a raw fish industry. In this case, stainless steel plate with frequent contact with fish was examined. One half of the plate was thoroughly cleaned and disinfected while the other half was cleaned and disinfected according to standard procedures.

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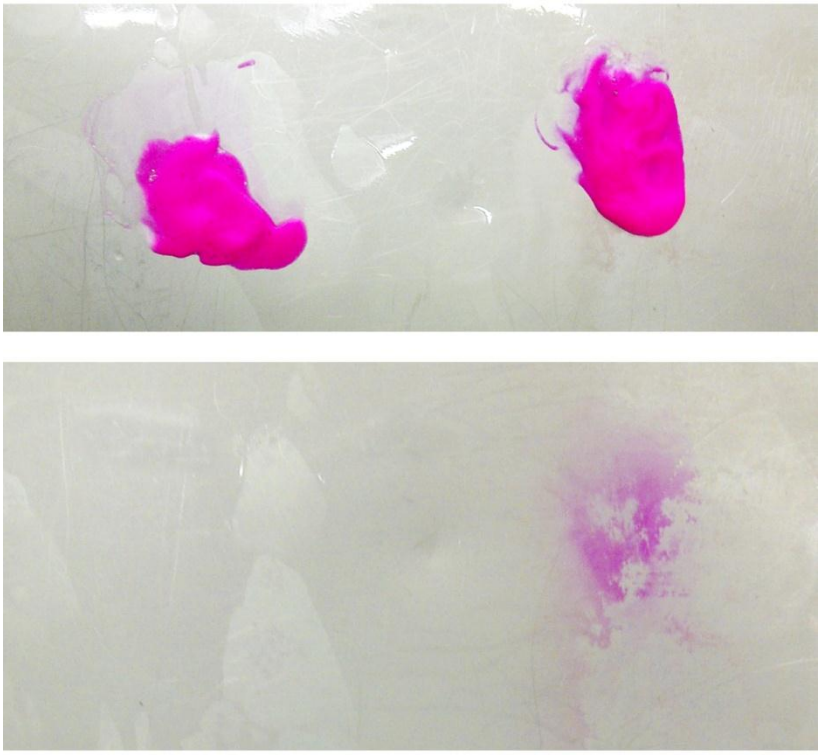

Figure 5. TBF 300 foam applied on a stainless steel plate with its left side thoroughly cleaned and its right side cleaned by standard procedures (upper image). After rinsing (lower image), residual coloration indicating biofilm presence is only observed on the right side, which was not subjected to a special hygiene treatment.

7. Certifications and regulatory compliance.

BETELGEUX and TBF 300 brands are property of **Betelgeux, S.L.** and they registered in Oficina Española de Patentes y Marcas.

Betelgeux holds patent protection for the composition of the **TBF300** BIOFILM DETECTION TEST the methodology for visual detection of biofilms based on application of dyes. The patent has been already awarded in Europe and further international protection is currently under way.

The packaging and commercialisation of **TBF 300** BIOFILM DETECTION TESTS complies with Spanish regulations on manufacture and commercialisation of aerosols (Real Decreto 1381/2009).

Labelling and classification of the product complies with European Union normative (Regulation (CE) 1272/2008 of the European Parliament and of the Council, of 31st March 2004 on classification, labelling and packaging of substances and mixtures.

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