

**DECLARATION OF COMPLIANCE**  
according to Regulation (EU) 10/2011 Annex IV

**- Treofan NND 20 -**  
**- Treofan NND 25 -**

**Manufacturer:**

**Treofan Group**  
Headoffice Treofan Group  
Treofan Germany GmbH & Co. KG  
Am Prime Parc 17  
65479 Raunheim  
Germany

**Status: European Union (EU)**

For the production of the polypropylene film only substances are used listed in Regulation **EU No 10/2011**. **Treofan NND** complies with the migration and other requirements of EU Regulations **1935/2004** and **2023/2006**.

When tested for overall migration using the following EU - recommended food simulants: 3% acetic acid (10 days at 40°C), 10% ethanol (10 days at 40°C) and olive oil (10 days at 40°C), resp. re-testing iso-octane (2 days at 20°C); the film passes the test - the migration from the film into each simulant being less than one third of the EU limit of 10 mg/dm<sup>2</sup> before the application of any permitted reduction factors.

The following substances subject to limitations and/or specifications may be present in the film.

Substance name	FCM substance No	SML [mg/kg]	SML (T) [mg/kg] (Group restriction No)	Restrictions and specifications	SM [mg/kg]
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	433	6			< 0,5
N,N-Bis(2-hydroxyethyl)alkyl (C8-C18)amine	19		(7) 1,2 mg/kg expressed as tertiary amine		< 0,2
Tetrakis(2,4-di-tertbutyl-phenyl)-4,4'-biphenylene diphosphonite	688	18			< 0,2
1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	689	6			< 0,5
1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	661	5			< 0,1
Stearic acid, zinc salt	106			Zinc = 25 mg/kg	< 0,5
Triisopropanolamine	292	5			< 0,1
Bis(2,4-di-tert-butyl-phenyl) pentaerythritoldiphosphite	652	0,6			< 0,1
Bis(2,4-dicumylphenyl)pentaerythritol-diphosphite	773	5			< 0,1

Regarding all substances instead of N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine the film is formulated that the specific migration limits cannot be exceeded under the normal recommended conditions of use even if all of the substances in it migrate into the food. According to Annex V Chapter 2 2.2.2 the verification of compliance with the limitations is not compulsory.

Regarding N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine tests have been carried out on comparable films by accredited laboratory confirming that the specific migration limit is met.

Contact conditions: 10 days @ 60°C  
 Simulants: A 10% ethanol  
 B 3% acetic acid  
 D2 vegetable oil

## Dual Use Additives

In the manufacture of the film the following substances are used which are subject to a restriction in food.

Substance name	FCM substance No / CAS No	E-number	Remark
Calcium stearate	1592-23-0	E 470a	Theoretical calculation about the level of the specific migration: <0,1 mg/kg
Silicium dioxide	504	E 551	Due to the chemical nature of the additive no potential migration into the food is to be expected.
Calcium carbonate	471-34-1	E 170	Due to the chemical nature of the additive no potential migration into the food is to be expected
Polydimethylsiloxane	575	E 900	Theoretical calculation about the level of the specific migration: < 0,1 mg/kg
Citric acid	139	E 330	Theoretical calculation about the level of the specific migration: <0,1 mg/kg

## Specification of the intended use or limitations

Type or types of food with which it is intended to be put in contact:  
 all types of food

Time and temperature of treatment and storage in contact with the food:  
 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.

Ratio of food contact surface area to volume used to establish the compliance of the material or article:  
 6 dm<sup>2</sup>/kg food

## Non Intentionally Added Substances (NIAS)

According to Article 19 of Regulation **EU 10/2011** a risk assessment regarding NIAS (non intentionally added substances) has been carried out in accordance with internationally recognised scientific principles on a representative selection of films from the range. In consequence compliance with the requirements of Article 3 of Regulation **1935/2004** at this level can be confirmed.

**Status: United States of America (US FDA)**

The unconverted and unprinted polypropylene film **Treofan NND** complies with the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of

Federal Regulations of the US Food and Drug Administration (FDA), under: **21 CFR 177.1520 (Olefin polymers)** provided it is used subject to limitations found in 21 CFR 177.1520 and in accordance with good manufacturing practices. Please note that the film should not be used for packaging or holding food during cooking.

## Heavy metals content

The heavy metals cadmium, lead, mercury and chromium<sup>VI</sup> are not intentionally used for the production of the unconverted and unprinted polypropylene films.

The sum of the heavy metals cadmium, lead, mercury and chromium<sup>VI</sup> incidentally present in this product is below 100 ppm and the film, therefore, complies with the limits set out in EC Directive **94/62/EC** on packaging and packaging waste and the **US CONEG Model Toxics Legislation**.

By observing the above regulations, the duty of care regarding the compliance of the product with legislation governing food contact applications has been fulfilled.

Although the product is intended for general food use (i.e. intended for contact with foodstuffs of all types) it is the responsibility of the user to verify its suitability for his own intended food application. No liability is accepted for losses arising from the inadequate suitability of the product for the particular foodstuff being used.

The content of this declaration is strictly confidential and should not be passed on to third parties. However in case your customer requires this information in order to assess compliance and measuring migration as required by law, you are entitled to pass them on to the customer or a neutral institute, under the strict obligation that the information is treated strictly confidential.

This declaration shall continue in effect for 1 year from its effective date unless it is modified before. If further information is required please do not hesitate to contact us.

Issued for and on behalf of Treofan Germany GmbH & Co. KG



Claudia Wehmeier  
Certified food chemist

fcc-foodcontactconsulting gmbh  
Kästnerstr. 1a  
74889 Sinsheim, Germany  
mailto: [claudia.wehmeier@treofan.com](mailto:claudia.wehmeier@treofan.com)

In each case all amendments of the above mentioned regulations or recommendations are included in their relevant versions up to the time of the issue of this statement.