



CERTIFICATE OF FOOD LAW COMPLIANCE

Product: PA/PE (Film Combiflex, Pouch Combivac, Pouch Combifresh G, Roll Combifresh G, Film Combiflex G, Amilen O, U, B)

This declaration is issued by Niederwieser S.p.A. as manufacturer and seller of the goods covered by this declaration.

We hereby declare that the materials called PA/PE (Film Combiflex, Pouch Combivac, Pouch Combifresh G, Roll Combifresh G, Film Combiflex G, Amilen O, U, B), according to the documentation in our possession, are in compliance with requirements of:

- Regulation 10/2011/EC and subsequent modifications and updates thereto and also with Regulation 1935/2004/EC and subsequent modifications and updates thereto.
- UK National Regulations 2012 about the Materials and Articles in Contact with Food, in particular 2619 for England, 2705 (W. 291) for Wales and 384 for Northern Ireland

The above mentioned materials are produced with the following components:

Composition
Nitrocellulose/polyurethane based inks (if printed), Polyamide, polyethylene (layer into contact with food)

It is also declared that the material contains substances subjected to restrictions in the aforementioned legislation. The specific migration limits and overall migration limits are respected with the following simulants:

- Simulant A (Ethanol 10% solution),
- Simulant B (Acetic acid 3% solution),
- Simulant D2 (Oil),

so it is suitable for direct contact with all kind of foodstuff

for prolonged period (>24 h) at ≤40°C, up to ≤70°C for 2 hours and all shelf life in refrigeration and freezing conditions)

The following substances, present as components (additives, monomers, etc.) of the raw materials used in the material,

- according to our current knowledge
  - based on analytical tests,
  - theoretical calculations (assuming that 1 kg of food comes into contact with 6 dm<sup>2</sup> of packaging material in accordance with Reg. 10/2011/EC, if applicable, equal to a volume/area ratio of 1.0 cm<sup>3</sup>/ml)
- statements from our suppliers,

are in compliance with specific restrictions imposed on the contact conditions and simulants mentioned above:

CAS Number	Substance	Restrictions	
-	Copper ***	SML = 5 mg/kg	
---	Zinc stearate	SML = 5 mg/kg	
000074-85-1	Ethylene	SML = 60 mg/kg	
000075-38-7	Vinylidene fluoride	SML = 5 mg/kg	
000077-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg	
000100-21-0	Terephthalic acid	SML = 7,5 mg/Kg	
000105-60-2	Caprolactam	SML = 15 mg/Kg	
000108-05-4	acetic acid, vinyl ester	SML = 12 mg/Kg	
000108-31-6	Maleic acid	SML = 30 mg/Kg. Expressed as Maleic acid	
000111-66-0	1-Octene	SML = 2,5 mg/dm <sup>2</sup>	
000112-84-5	Erucamide	N.D. (not detectable)	
000116-15-4	Hexafluoropropylene	N.D. (not detectable)	
	Declared PFAS substance as polymerization catalyzer, not present as not detectable		
000121-91-	Isophthalic acid	SML = 5 mg/Kg	
5 000122-	Triisopropanolamine	SML = 5 mg/kg	
20-3	Hexamethylenediamine	SML = 2,4 mg/Kg	
000124-09-	1 - Hexene	SML = 3 mg/Kg	
4 000592-	Octadecyl 3- (3,5-di-tert-butyl-4- hydroxyphenyl)	SML = 6 mg/Kg	
41-6	propionate		
002982-79-7	Trimethoxyvinylsilan		SML = 0,05 mg/Kg
002988-02-7			

\*\*\* Presents in blue-in-mass colored film



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According to our current knowledge, we hereby declare that the product contains substances regulated by Regulations 1333/08/EC and 1334/08/EC (otherwise called "Dual Use" additives) which are listed in the following table:

EU Number	Substance
E 1521	Polyethylene glycol
E 170	Calcium carbonate
E 171	Titanium Dioxide */**
E 180	Lithol Rubine BK (Pigment Red 57:1) *
E 330	Citric Acid
E 470 a	Mono and diglycerides of fatty acids (Calcium, potassium, sodium salts)
E 553 b	Talc
E 570	Stearic Acid
MCA n. 411	Carbon black ****

\* Present only if the materials are printed

\*\* Presents in white-in-mass colored film

\*\*\*\* Presents in cold black-in-mass materials

According to experimental data and/or theoretical calculations, these substances meet the relevant requirements of Regulation 10/2011/EC (Art. 11 paragraph 3) and subsequent amendments and supplements, and Regulation (EC) No. 1935/2004, Article 3, Article 11, paragraph 5, Article 15 and Article 17.

The end user of Niederwieser's packaging material has the duty to inform our company about possible restrictions on additives or aromas used in the production of foodstuff packed.

Although all the raw materials used are of low sensory impact, the end user of the packaging is advised to check the organoleptic suitability of the material with the product to be packaged.

This declaration is issued by an operator of the sector, appointed by Niederwieser S.p.A., on the basis of knowledge of its industrial process and the technical characteristics of the materials mentioned, in full transparency and with adequate information about the substances used or any degradation products for which Annexes I and II of Regulation 10/2011/EC establish restrictions and/or specifications, so as to allow downstream commercial operators to ensure compliance with the same Regulation.

We hereby declare that the following documentation is available for the competent Authority:

- test reports on the finished product
- the appropriate declarations and technical data sheets issued by the suppliers of raw materials
- other supporting documentation required pursuant to Reg. 1935/2004/CE, art.16, paragraph 1

**PRIMARY AROMATIC AMINES**

The migration of primary aromatic amines (PAA) is in accordance with the limits set in Annex II of Reg. 10/2011/EC, modified by Reg. 1416/2016/EC and Reg. 1245/2020/EC, under the above mentioned conditions of use.

**GUARANTEE AND VALIDITY**

We recommend storing the material in sheltered, clean and dry place. The material must not be exposed to sources of heat or sunlight and it must be stored at temperatures between +10 and +40°C and at relative humidity between 50 and 75%. For the warranty terms of the material, please refer to the website <http://www.niederwiesergroup.com> at the specific "general terms and conditions" section.

According to our internal procedures regarding the documents management, in compliance with the BRC Packaging Standard, it is not necessary to revise the date of this document, as there is an automatic system of legislative updating for which updates are evaluated and promptly incorporated into our system. This declaration will be replaced with a new one when there are substantial changes in the production of the material that can change certain essential compliance requirements or when the aforementioned legislative references are modified, updated or repealed by new ones that require a new verification for compliance purposes.



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In case of materials in reels, it is recommended to unroll and not to use the first loop of plastic film wrapped on the outside of the reels and the final one whose surface is directly attached to the mandrel: even if it is a safe material coming from the same productions, these parts of film may be more subject to contamination. The user of Niederwieser's material should satisfy himself as to the suitability of our products for the intended application and the current regulatory regime. Therefore, we disclaim any liability for damages arising from the non-suitability of our products for the effected application. This guarantee of suitability for contact with foods becomes null and void if the materials are used in conditions or with foodstuffs other than those specified above, if other substances are added and/or processing performed that may modify the properties of the said materials. Such uses exonerate Niederwieser S.p.A. from all liability and transfer to the end user all responsibility for verifying the suitability of the materials for use in the new conditions.

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This annex is issued by Niederwieser S.p.A. with the sole purpose of providing additional and complementary information to the document Declaration of suitability for food contact (E-CD02).  
The information contained in this document is non-binding, i.e. there is no regulatory requirement for the release of such information.

#### MOSH and MOAH

MOSHs (Mineral Oil Saturated Hydrocarbons) are categorized as saturated aliphatic hydrocarbons.

MOAH (Mineral Oil Aromatic Hydrocarbons) are categorized as hydrocarbons that have 1 to 4 aromatic rings and are considered more toxic than MOSH, because of the benzene rings contained.

Concerning plastic materials, MOSH and MOAH are known as POSH, which are categorized as oligomers present in the polyolefin of plastic packaging.

The main source of MOSH and MOAH are regenerated cardboard packaging that is the higher risk contamination source for foodstuff, as these hydrocarbons can potentially migrate - more if of low molecular weight (with atoms of C<24), lower or negligible quantities if of high molecular weight (with atoms of C>4).

At present, since there are no official opinions on the toxicology of these substances and since there is no shared EU regulation imposing limits for MOSH and MOAH, the guidelines of the BfR and the German Ministry of Agriculture have been taken as reference for the indicative limits of mineral oil concentrations in food and packaging, in particular:

- specific migration limit for MOAH in food = 0,5 mg/kg
- no specific migration limit for MOSH
- a preferable use of functional barriers in the packaging (such as polyamides or EVOH).

Sensitive to the problems of MOSH and MOAH Niederwieser S.p.A. - Food Packaging Division performed appropriate worst-case analyses, therefore, so, regarding the packaging materials referred to this document, we declare:

- absence of MOAH;
- MOSH contents in quantities not subjected to migration or subjected to migrations with lower values than overall and specific migration values.

#### NIAS – Not Intentionally Added Substances

NIAS are not intentionally substances that are added in the manufacture and marketing of the material and articles made of plastic. These are intended to come in contact with food, such as contamination in the substances used, disintegration or reaction products that have formed during production or reaction interim products.

Whether the non-intentionally added substances correspond to first section of Regulation (EC) Nr. 1935/2004 or not must be assessed in accordance to the internationally recognized scientific principles via risk assessment (see Section 19 of Regulation (EC) Nr. 10/2011).

The NIAS screening was performed by gas chromatography and flame ionization detector (GC-FID) according to the internal standard.

After toxicological evaluation the measured values of these substances complies with the requirements of the Regulation (EC) Nr. 10/2011.

#### ABSENCE OF VARIOUS SUBSTANCES

On the basis of our suppliers' declarations, our production process' knowledge and on the basis of the risk assessment in compliance with the BRC Global Standard requirements, we hereby declare that in the product/s supplied the following substances are not added or are not intentionally used:

- nanomaterials, nanoparticles and nanotechnologies
- Photo-initiators of printing -UV as 2-Isopropyltioxantone (ITX)
- PFAS substances
- 4-methylbenzophenone (CAS No. 134-84-9) and Benzophenone (CAS No. 119-61-9)
- BPA or Bisphenol A (2,2 bis (4- hydroxyphenyl) propane) in compliance with Regulation 213/2018/EC
- other bisphenols as BPS (Bisphenol S) o BPF (Bisphenol F) etcetera
- BADGE, BFDGE and NOGE in compliance with Regulation 1895/2005/EC
- phthalate-based plasticizers
- ionizing treatments

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- fluorocarbons or perfluorocarbons (PFC)
- quaternary ammonium compounds
- recycled materials
- PVC and chlorinated compounds (with the exception of materials containing PVDC lacquered polyester, PET-S)
- E265 (dehydroacetic acid)
- Melamine
- 2,4-pentandione (Acetylacetone)
- Titanium Acetylacetonate (TAA)
- GMOs (genetically modified organisms)
- carcinogenic, mutagenic or genotoxic substances present in the California "Proposition 65 list";
- Nitrosamines
- Allergens (the risk of contamination is included in the HACCP plan, evaluated as low and managed through appropriate GMPs)
  - o Cereals containing gluten (ie wheat, rye, barley, oats, spelled, kamut or their derived strains) and derived products
  - o Crustaceans and products based on crustaceans
  - o Eggs and egg products
  - o Fish and fish products
  - o Peanuts and peanut-based products
  - o Soy and soy products
  - o Milk and milk products (including lactose)
  - o Nuts (almonds (*Amigdalus communis* L.), hazelnuts (*Corylus avellana*), common walnuts (*juglans regia*), cashew nuts (*Western anacardium*), pecans (*Caya illinoiesis* -Wangenh- K. Koch), brazil nuts (*Bertholletia exelsa*), pistachios (*Pistacia vera*), Queensland nuts (*Macadamia temifolia*) and derived products
  - o Celery and products based on celery
  - o Mustard and mustard-based products
  - o Sesame seeds and sesame seed products
  - o Sulfur dioxide and sulphites in concentrations higher than 10 mg/kg or 10 mg/l expressed as SO<sub>2</sub>
  - o Lupins and products based on lupins
  - o Molluscs and products based on molluscs)
- products derived from any kind of animals and / or substances called "Harām", such as:
  - o Pork or their derived products (such as jelly, etc.)
  - o Reptiles, amphibians, insects and their derivatives
  - o Any type of animal (carnivores, marine, birds, etc.) alive or dead
  - o Any kind of food and / or ingredients such as enzymes, gelatin, emulsifiers and flavourings
  - o Any kind of blood and from any living being
  - o Human derivation products
  - o Acetic acid
  - o Beta-apo-8-carotenes dye (C30)
  - o Apocarotenal dye (E160e)
  - o Colorant Carmine / Ladybird (E120)

The absence of the above-mentioned 'Harām' substances makes it possible to declare the material covered by this 'Halāl' declaration or usable for and in contact with food in accordance with the rules of Islamic law.

With regard to the possible presence of alcoholic substances in the mentioned products, we can state the following:

- some types of alcohol are used as carrier solvents for inks and adhesives in order to be able to technologically print inks (in case of printed films) and/or laminate plastic materials into films (in case of laminated films);
- for our quality and food safety system certified in compliance with BRC Global Standard, we need to guarantee health and hygiene by contact between products and surfaces or hands of operators: for these reasons we use appropriate disinfectants with low alcohol content; we do not exclude that traces of alcohol from the disinfectants used may have been transferred to the products;

anyway, the presence of residues of alcoholic substances is monitored according to appropriate control plans; this allows us to declare a total presence of alcoholic substances never exceeding 10 mg/m<sup>2</sup> as the total of all alcohols and never exceeding 5 mg/m<sup>2</sup> for each single alcoholic substance.

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However, it is our duty to inform you that not all the substances and compounds mentioned above are subject to specific research and analysis tests, therefore the presence of the substances indicated as the effect of any contamination not depending on our manufacturing process cannot be excluded.

**PRESENCE AND SUITABILITY OF OXY-DRY POWDER**

We inform you that in the products supplied could be detectable the presence of white powder: the same, called "oxy-dry", is a vegetable food powder based on starch, free of GMOs and allergens (as well as all the substances referred to in the previous paragraph).

The same powder is used to facilitate the sliding of the material in the machine for the realization of the pouches and the easy-opening of the same, to help the sliding of the films on the Customer's machines and/or to avoid effects of blocking of the reels for some particular materials (i.e. peelable materials).

For the product supplied, the visibly more significant presence in some pouches or for a few metres is not excluded; anyway, this presence does not compromise the quality of the product supplied.

Anyway, we guarantee that this "oxy-dry" powder is suitable for use in direct contact with foodstuff.

**MICROBIOLOGY**

Based on the risk assessment and in accordance with the procedures implemented in compliance with BRC Global Standard requirements, we confirm that analytical tests are carried out to monitor the microbial load (including pathogenic) on supplied equipment, work environments and products.

We hereby declare that the history of the monitoring carried out provides negligible values compared to our defined internal critical limits, therefore the materials referred to in this declaration do not constitute a substrate for microbial proliferation and we can declare them free from microbiological contamination.

**INKS COMPLIANCE**

Niederwieser S.p.A. herewith declares that all inks and varnishes used for printing its plastic packaging materials (films and pouches) are bought by companies with a quality managing system of control which respects the following principles :

1. All raw materials used for production of inks are made excluding the use of categories or individual substances which are classified as Carcinogenic, mutagenic or toxic for reproduction on the base of what is listed in CEPE/EuPIA exclusion list (version 7th- April 2011).
2. All inks and varnishes are produced following "Good Manufacturing Practices for the production of Packaging Inks formulated for use on surfaces not in contact with food packaging food and objects intended to come into contact with the foods (GMP)" issued by CEPE/EuPIA (version March 2009)
3. All inks products are engineered either to minimize or exclude potential migration through printing substrate or set-off effect from the outer side moulded to the surface in contact with the food when they are stacked or wound in reels, taking into account the purpose for which they were designed.

Niederwieser S.p.A. either in the first printing step or in all following production steps, applies a quality managing system of control certified in compliance with BRC Global Standard for packaging and packaging materials based on risk assessment: this means that machines and inks working parameters are under strict controls as well as quality parameters, ensuring, at the end, a very low risk of set-off.

Inks and varnishes used for printing plastics are free of BPA or Bisphenol A (2.2 bis (4- hydroxyphenyl) propane) in compliance with Regulation 213/2018/EC.

On the basis of our current knowledge, plastic substrates chosen for printing show an adequate barrier effect in order to avoid migration of unwished substances from inks to foodstuff packed.

Solvent retention is kept under control in order to have a very low risk of organoleptic contamination due to solvent residues in the printed package






**ENVIRONMENTAL ASPECTS**

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The material complies with the requirements of Directive 94/62/EC and subsequent amendments including the essential requirements defined in Legislative Decree No. 152 of 03/04/2006 (Part IV) articles 217 - 226) for the following reasons:

- Prevention by source reduction – Minimisation of dangerous substances or preparations – EN 13428 (July 2004 edition). The total heavy metal content is far below 100 ppm and materials do not contain substances classified as dangerous for the environment (Directive 1999/45/EC). Prevention by source reduction – Minimisation of packaging weight/volume - EN 13428 (July 2004 edition). Niederwieser S.p.A's materials, depending on final applications and information received from consumers/users, have been designed to ensure that the weight and/or volume of their constituent is at the minimum commensurate with the maintenance of packaging functionality, safety, hygiene and acceptability to user of packed product. Recoverability in the form of energy – EN 13431 (July 2004 edition).
- Materials after use can be incinerated supplying a positive calorific gain, so that they contribute to an energy recovery process.

The materials produced by Niederwieser S.p.A. can be identified with Möbius cycle symbols according to the following criteria:

Material / Brand	Möbius cycle symbol
Combiflex, Amilen, CombiFresh, Combivac without Aluminium	 OTHER
Combiflex, Combivac with Aluminium	 C/LDPE
Combiflex R, Nextflex (MPOX)	 OTHER
Combiflex R-PE, Nextflex-PE (MPOX-PE)	 LDPE
Combiflex R-PP, Nextflex-PP (MPOX-PP)	 PP

Anyway, all materials must be wasted in the separate plastic collection.

**ORIGIN AND TYPOLOGY OF RAW MATERIALS**

We declare that the materials supplied are produced from virgin raw materials, therefore with total absence of recycled materials.

We also declare that all raw materials and finished products supplied to you are produced preferentially in the European Union (preferably Italy and Germany).

**TRACEABILITY**

The traceability of the material, in compliance with Regulation 1935/2004/EC and with the requirements of the BRC Global Standard for packaging and packaging materials, is guaranteed by a systematic management of batches for each production phase or marketing and subsequent products' labelling with such lot numbers.

**CERTIFICATIONS AND GMPs**

Niederwieser S.p.A. produces and sells its materials in accordance with a documented self-control's system, as well as quality control certified and in compliance with the BRC Global Standard for packaging and packaging materials. This, together with compliance with good manufacturing practices (GMPs), guarantees compliance with the provisions of Regulation 2023/2006/EC in force from 1 August 2008.

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