

**Product: Pouch PA/PE, Pouch Combifresh G, Roll Combifresh G, Film Combiflex PA-PE, Film Combiflex G, Amilen O/U/B-PA-PE**

We hereby declare that the materials called **Pouch PA/PE, Pouch Combifresh G, Roll Combifresh G, Film Combiflex PA-PE, Film Combiflex G, Amilen O/U/B-PA-PE**, 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. The above mentioned materials are produced with the following components:

- 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 (including hot-filling, up to ≤70°C for 2 hours, up to ≤100°C for 15 minutes 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>2</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
---	Zinc stearate	SML = 5 mg/kg
000074-85-1	Ethylene	SML = 60 mg/kg
000100-21-0	Terephthalic acid	SML = 7,5 mg/Kg
000105-60-2	Caprolactam	SML = 15 mg/Kg
000112-84-5	Erucamide	N.D. (not detectable)
000121-91-5	Isophthalic acid	SML = 5 mg/Kg
000122-20-3	Triisopropanolamine	SML = 5 mg/kg
000124-09-4	Hexamethylenediamine	SML = 2,4 mg/Kg
000128-37-0	2,6-di-tert-butyl-p-cresol (BHT)	SML = 3 mg/Kg
000301-02-0	Oleamide *	SML = 60 mg/Kg
000592-41-6	1 - Hexene	SML = 3 mg/Kg
026523-78-4	Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	SML = 30 mg/kg

\* Present only if the materials are printed

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 170	Calcium carbonate
E 171	Titanium Dioxide*/**
E 180	Lithol Rubine BK*(Pigment Red 57:1)
E 559	Aluminium silicate *

\* Present only if the materials are printed

\*\*present only in white coloured films

According to experimental data and/or theoretical calculations, these substances are in accordance with the requirements of Reg. 10/2011/EC, Art.11, paragraph 3. 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.

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

- test reports on the finished product

**Product: Pouch PA/PE, Pouch Combifresh G, Roll Combifresh G, Film Combiflex PA-PE, Film Combiflex G, Amilen O/U/B-PA-PE**

- 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, to the conditions of use mentioned above.

**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 >24).

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.

**ABSENCE OF VARIOUS SUBSTANCES - NIAS**

On the basis of our suppliers' declarations, our production process' knowledge and on the basis of the risk assessment in compliance with the BRC 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)
- 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
- 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)

**Product: Pouch PA/PE, Pouch Combifresh G, Roll Combifresh G, Film Combiflex PA-PE, Film Combiflex G, Amilen O/U/B-PA-PE**

- carcinogenic, mutagenic or genotoxic substances present in the California "Proposition 65 list";
- Nitrosamines
- any other NIAS
- 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 Alcoholic substances
  - 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.

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.

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Based on the risk assessment and procedures implemented according with BRC requirements, we confirm that analytical tests are performed in order to monitor the microbial load on the products supplied and any eventual contamination.

We hereby declare that the history of the monitoring performed provides negligible values with respect to our defined internal critical limit, therefore the materials referred to in this declaration do not constitute a substrate for microbial proliferation.

**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 molded 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**

The material complies with the requirements of Directive 94/62 / EC and subsequent amendments (the last of which is Directive 2004/12 / EC) 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.

**ORIGIN AND TYPOLOGY OF RAW MATERIALS**

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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' labeling 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.

#### 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.

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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