According to Reg. (EU) No 10/2011 - Annex IV

EK-DECLARATION

Registration no.: **3015**

Valid until: **14.03.2026**

THE FOOD CONTACT COMPLIANCE DECLARATION OF EMBALLASJEKONVENSJONEN, EK (THE NORWEGIAN PACKAGING CONVENTION)

2	Business operator:	**Tega Group AS**
2	Address:	Energivegen 20, 4056 Tananger, Norway
3	Type of packaging:	Disposable rubber gloves
3	Model number:	**NG-10, NG-11, NG-12, NG-13, NG-14, NG-15, NG-16, NG-17, NG-18, NG-19. NG-20, NG-21, NG-22, NG-23, NG-24, NG-25, NG-26, NG-27, NG-28, NG-29.**
3	Material composition:	Nitrile rubber (NBR), pigment.

4 The above listed packaging material(s) is (are) manufactured in accordance with and fulfil the requirements of the European Regulation (EC) No 1935/2004 as specified below. Exception: sensory evaluation is not performed, see article 7 below.

4	References to regulation: (see the backside for more information)	Regulation (EC) No: 1935/2004, 2023/2006. BfR XXI, BfR XXI/1. Relevant parts of Regulation (EU) No: 10/2011 with all its amendments. Swiss ordinance 817.023.21.
5	Relevant information[1]: (see the backside for more information)	Are in compliance with the Overall Migration limit Are in compliance with Specific Migration Limit (SML) for substances which have a SML Contain Dual Used Additives (DUA): E170 (Titanium dioxide). For plastics: raw materials are in accordance with Regulation (EU) No: 10/2011 (w/Amendments).
6	Usage/ specifications[1]:	Disposable nitrile examination gloves and protective gloves. Suitable for short term contact with all types of food (0-40 °C for ≤ 30 min).
7	Additional information[1]:	A sensorial examination using distilled water as food simulant at 23 °C for 24 hours has been performed. Additional tests must be performed to be able to exclude deterioration of the sensory (smell and taste) characteristics of the actual foodstuffs.

8 We will inform the user and the Norwegian Packaging Convention, EK, as required in Matkontaktforskriften §10, when substantial changes in the production bring about changes in the migration or when new scientific data are available. Documentation is updated continuously and is forwarded to EK when the EK-declaration is renewed.

9 Date: 14.03.2024 ..... Stamp: TEGA GROUP AS NO 925 676 608 ENERGIVEGEN 20 4056 TANANGER NORWAY Signature: (Business operator)[2] .....

10 Stamp of the Norwegian Packaging Convention, EK:

10 Written documentation controlled by: Ida-Helene Spydevold Date: 14.03.2024

This Declaration is valid only when bearing the EK-stamp and registration number.

EMBALLASJEKONVENSJONEN, c/o Nofima AS, Postboks 210, N-1431 Aas, Norway
www.emballasjekonvensjonen.no

1) See the backside, 3rd section: "Information..."; 2) Person responsible for the food contact regulation

EK Declaration page 2 (backside)

The EK-Declaration contains information required by Annex IV Regulation (EU) No 10/2011 regarding Declarations of Compliance.

If the material will be used as a component in finished contact materials the EK-Declaration shall also include information about relevant restrictions (SMLs) according to Annex IV.

Information under art. 4, 5, 6 and 7 on the front page – NB! This will be important information to the user of the EK-Declaration

4. The majority of the supporting material specific documentation from the producers are referring to the regulations listed
5. Give(s) information of any substances also listed in the food regulation (Dual Use Additives - DUA). An enclosure may be used.
6. Give(s) actual or general applications for types of foods, storage time and temperature, and any area/volume restrictions for the material
7. Standard text from EK is that a material generally is not tested for absence of smell and taste deterioration unless this is specified here. Under point 7, use of the functional barrier concept should be indicated.

Certification – Application

The applicants for the declaration shall obtain updated versions of conformity statements and other documentation from the producers of raw materials, the producers of packaging materials and the test laboratories, depending on how one is affected by the requirements in the regulations. EU Regulations and Directives are advanced as EK reference 6 months after adoption at the latest. Filled in EK-Declaration and a Documentation Summary form shall be forwarded to the EK-Secretariat at Nofima AS, with documentation enclosed. The secretariat issues a stamped EK-Declaration after examining the documents. Checklists or guidance is available from the EK-Secretariat.

Extracts from the Articles of the Packaging Convention, EK

Article 1. Main objective (first section)
The objective of the packaging convention is to assist the members to ensure compliance with the Norwegian Matkontaktforskriften. This requires that there shall be no transfer of components from materials at levels that:

- Would constitute a health hazard,
- Cause some unacceptable change in the composition of the food product,
- Lead to a deterioration of the sensory properties of the food

Article 5. The EK-Declaration
The EK-Declaration is issued bases on documentation received and checked by the Secretariat of EK. The EK-Declaration is valid for 2 years.

Article 8. Requirements for documentation in EK
The requirements for documentation, regarding the EK-Declaration, are based on statements, calculations, or certificates of analyses, compliant with all the points in the EK safety requirements. An EK-Declaration can be issued after:

- Control of relevant and supporting documentation from raw material suppliers, packaging suppliers of material and objects or,
- The demonstration of valid statements and certificates from known and neutral institutions

The requirements of Declarations of Compliance and documentations are a part of Matkontaktforskriften. Detailed requirements are drawn up based on the Guidance Document for Matkontaktforskriften from Mattilsynet.

EK Requirements – European and national regulations, recommendations and resolutions – all materials are not included

FOR ALL MATERIALS: Regulation (EC) No 1935/2004 and (EC) No 2023/2006. However, the requirement in Regulation (EC) No 1935/2004 for absence of organoleptic deterioration can only be ensured after testing with the actual foodstuff.

PLASTIC: Regulation (EU) No: 10/2011, 1282/2011, 1183/2012, 202/2014. Regulation (EU): 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/1338, 2020/1245, 2023/1442, 2023/1627. NB! According to these regulations relevant information about Dual Use Additives (DUA) must be presented for the food industry.

Where detailed EU-measures are not yet established, other recommendations may be used (BfR, Swiss Ordinance, Warenwet, FDA, etc.).

PAPER: BfR XXXVI (or Warenwet/FDA)

PLASTIC COATED PAPER: For the plastic, see PLASTIC; for the paper see PAPER

ABSORBERS based on polyacrylates: BfR LIII + migration limits for PLASTIC

METALS: CoE (2013), CM/Res(2020)9

GLASS: Warenwet Chap. V

ADHESIVES: BfR XXVIII and parts of Regulation No 10/2011

COLORANTS: Swiss Ordinance 817.023.21 or BfR IX and parts of Regulation No 10/1011

PRINTING INKS: EuPIA Guideline on Printing Inks, AP(89)1 or Swiss Ordinance 817.023.21, and parts of Regulation No 10/2011

COATINGS: Regulation (EC) No 1895/2005 and parts of Regulation No 10/2011, as well as FDA §§ 175.210 to 175.390

For other materials than plastics: Some alternatives are given in Matkontaktforskriften from the Norwegian Food Safety Authority (in Norwegian): https://lovdata.no/dokument/SF/forskrift/1993-12-21-1381

Documentation requirements

Compliance with the EK-requirements must be documented in writing.

- Positive list and other list requirements: Declarations of Compliance from producers of the raw materials and the packaging producers
- Restrictions (OM, SMLs, QMs): Declaration of Compliance from raw material producers and/or the packaging producer in addition to analytical test reports from test laboratories regarding migration, or calculations/modelling.
- Declarations of Compliance from raw material producers shall include reference to Regulation (EC) No 1935/2004 and (EC) No 2023/2006. From the packaging producers and the importers/distributers, the Declarations of Compliance shall be more detailed by also listing the requirement they fulfil. For example, traceability, labelling, quality assurance, quality control and documentation. More information is obtainable from the EK-Secretariat.

Testing, modelling and calculation shall be according to EN-standards and other standards available. Where applicable the test conditions (temperature, time, simulants) shall be according to Regulation (EU) No 10/2011(with Amendments).

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