According to Reg. (EC) No 10/2011 –Annex IV

EK-DECLARATION

Registration no.: **2531**

Valid until: **03.11.2017**

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

2	Business operator:	**Vartdal Plastindustri AS**
2	Address:	6170 Vartdal
3	Type of packaging:	Bags for cooling of fish in boxes
3	Trade name/Art. no.:	Gel-Ice
3	Material composition:	PELD/PELLD film + polyacrylate gel

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 9 below:

5	References to regulation:	Regulation (EC): No 1935/2004, No 2023/2006, No 10/2011, No 1282/2001, No 1183/2012, No 202/2014 and No 450/2009
7	Relevant information[1]:	Are in compliance with the Over All Migration limit Are in compliance with Specific Migration Limit (SML) for substances which have a SML – max migration less than 50% of limit. For plastics: raw materials are in accordance with No: 10/2011 (w/Amendments) Contains DUA: E470a, E570, E551, E514, E1521. DUAs will contribute with less than 5% of limits listed in food regulation.
8	Usage[1]/ specifications[1]:	Bags for cooling of fish in boxes
9	Additional information[1]	Additional tests must be performed to be able to exclude deterioration of the sensory (smell and taste) characteristics of the actual foodstuffs.

We will inform the user and the Norwegian Packaging Convention, EK, 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.

Vartdal Plastindustri AS
6170 Vartdal
Org.nr. 970 890 513 MVA

4 Date: 26.01.16 Stamp: Signature: (Business operator)[2] Sandre Vartdal

1 Stamp of the Norwegian Packaging Convention, EK:

1 Written documentation controlled by: Isabell Lien Isabell Lien Date: 18.12.2015

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

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

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

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

If the material will be used as component in finished contact materials the EK-declaration shall also include information about relevant restrictions (SMLs) according to pnt 6 of ANNEX IV.

Information under pnt 7, 8 and 9 on the front page – NB! This will be important information to the user of the EK-Declaration

7. give(s) information of any substance also listed in the food regulation, Dual Use Additives (DUA), that the food producer should be aware of. For confidential reasons you may use an enclosure to specify.
8. give(s) actual or general applications for types of foods, storage time and temperature, and any area/volume restrictions for the material.
9. 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 pnt 8 use of the functional barrier concept should be indicated – here one may also list SMLs when the material is a component of the finished material

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 regulation. 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 Mat, with documentation enclosed. The secretariat issues a stamped EK-declaration after examining the documents. Check-lists or guidance are available from the EK-secretariat.

Extract from the articles or the Packaging Convention, EK

Article 1. Main objective (first section)
The objective of the packaging convention is to assist its members to secure packaged foodstuffs against transfer of components from the packaging material which can:
- endanger human health
- bring about an unacceptable change in the composition of the foodstuffs or deterioration of the organoleptic (smell & taste) characteristics thereof.

Article 5. The EK-declaration
The declaration of Packaging Convention, EK-declaration, is based on written conformity statements from the converters and the producer of raw materials, which is controlled by the Packaging Convention secretariat. The EK-declaration is valid for 2 years.

Article 8. The Convention's demand for documentation
The Convention's demands for documentation are conformity statements and test reports according to all elements in the safety demand of the Convention.
An EK-Declaration will be issued after:
- control of supporting documentation from the produces of the packaging raw materials, or
- presentation of complete declarations/certificates from know institutions

Demands for written documentation are a part of the EC regulation. Detailed requirements are formed on the basis of the regulation and notes and guidelines from Mattilsynet - The Norwegian Food Control Authority.

EK Requirements – European and national regulation, and recommendations and resolutions for the majority of the materials

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 ensured after testing with the actual foodstuff.

PLASTIC: Regulation (EC): No 10/2011, Regulation (EC) No 1282/2011, Regulation (EC) No 1183/2012 and Regulation (EC) No 202/2014. NB! According to this regulation relevant information about Dual Use Additives must be presented for the food industry. Where detailed EU-measures are not yet established the BfR-Recommendations I - LIII (or Warenwet or FDA) can be used

PAPER: BfR- Recommendations XXXVI (or Warenwet/FDA)

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

ABSORBERS based on polyacrylates: BfR- recommendation LIII + migration limits for plastics

METALS: Warenwet Chap. IV or EN standards

GLASS: Warenwet Chap. V

ADHESIVES: BfR-recommendation XXVIII and some parts of the plastics Regulation

COLORANTS: BfR-recommendation IX and some parts of the plastics Regulation

PRINTING INKS: EuPIA Guideline on Printing Inks and some parts of the plastics Regulation

COATINGS: Regulation (EC) No 1895/2005, some parts of the plastics Regulations and FDA §§ 175.210 to 175.390

For other materials than plastics: Some alternatives are given in the Food Contact Guideline, from Norwegian Food Safety Authority (in Norwegian) http://www.mattilsynet.no/regelverk/veiledere/mat

Documentation

Compliance with the EK-requirements in written documentation.

- Positive list and other list requirements: Compliance declarations from producers of the raw materials and the packaging producers.
- Restrictions (OML, SMLs, QMs): Compliance declarations from raw material producers and/or the packaging producer and/or test laboratories regarding migration, modelling and/or calculation.
- General requirements of Regulation (EC) No 1935/2004 and (EC) No 2023/2006: Compliance declarations 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 compliance declarations shall be more detailed by also listing the requirement they fulfil: e.g. traceability, labelling, quality assurance, quality control and documentation. More information and examples are 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 Regulation (EC) No 10/2011 and EU-directives 82/711/EEC, 85/572/EEC, 93/8/EEC and 97/48/EC.

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