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### **Product Safety and Regulatory Compliance**

#### **Allergens: Statement for DARAFORM® 6411MF**

(F539)

REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers

With reference to the status of this product under the subject regulation, we would point out that this product is intended for use in the manufacture of food packaging. Therefore it does not come within the scope as defined in Article 1.

Nevertheless, we confirm that Darex Packaging Technologies does not intentionally use the following substances as additives or raw materials in this product. From process knowledge, these substances are not expected to be in this product and therefore the levels are not evaluated.

For information purposes, the specific substances concerned listed in Annex II are listed below:

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:
  - (a) wheat based glucose syrups including dextrose (\*);
  - (b) wheat based maltodextrins (\*)
  - (c) glucose syrups based on barley;
  - (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;
2. Crustaceans and products thereof;
3. Eggs and products thereof;
4. Fish and products thereof, except:
  - (a) fish gelatine used as carrier for vitamin or carotenoid preparations;
  - (b) fish gelatine or Isinglass used as fining agent in beer and wine;
5. Peanuts and products thereof;
6. Soybeans and products thereof, except:
  - (a) fully refined soybean oil and fat (\*)
  - (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
  - (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
  - (d) plant stanol ester produced from vegetable oil sterols from soybean sources;
7. Milk and products thereof (including lactose), except:
  - (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
  - (b) lactitol;
8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;
9. Celery and products thereof;
10. Mustard and products thereof;
11. Sesame seeds and products thereof;
12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO<sub>2</sub> which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;

Req ID 11868



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- 13. Lupin and products thereof;
- 14. Molluscs and products thereof.

(\*) and the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.

**Bisphenol A (BPA): Statement for DARAFORM® 6411MF**

(F556)

We hereby confirm that based on information provided by our raw materials suppliers no Bisphenol A (CAS# 80-05-7) is intentionally used in the manufacture of the constituent raw materials or of this product as supplied by Darex Packaging Technologies.

From process knowledge, this substance is not expected to be in this product and therefore the levels are not evaluated.

**Commission Regulation (EU) No 10/2011: Statement for DARAFORM® 6411MF**

(F860-1)

When properly applied and if necessary dried or cured in accordance with our application recommendations, we confirm that this product, as supplied by Darex Packaging Technologies is compliant with Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [and amendments].

**EU Food Law - Non-Confidential Disclosure: Statement for DARAFORM® 6411MF**

(F800-19)

General Condition Section

This product is manufactured under good manufacturing practices so that the finished products containing it can comply with the provisions of the EU Framework Regulation (EC) No.1935/2004 on food-contact materials. However, it is the responsibility of manufacturer of the finished food-contact article to ensure that all relevant regulatory or legislative limitations and specifications are met, including compliance with Article 3 of the Framework Regulation.

Specific statement

To assist customers in the assessment of their packaging against the requirements of EU Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October, 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, the following information is given for this product, as supplied by Darex Packaging Technologies :

It is manufactured only from materials in compliance with either (i) Commission Regulation (EU) No 10/2011 [and amendments] or (ii) a valid member state regulation such as the Netherlands VGB or BfR Recommendations in Germany.

As a consequence, in addition to the overall migration limit of 10 mg/dm<sup>2</sup> of food contact surface, specific restrictions which apply are complied with.

With reference to the EU status, when properly applied and if necessary dried or cured in accordance with our application recommendations, we confirm this product is compliant with EU Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

This is confirmed by tests carried out at an independent testing laboratory (See enclosed) which confirm satisfactory migration and organoleptic performance of this product.

Enclosure: SQTS general statement dated 3 October 2014

This product is suitable for use with aqueous and alcoholic beverages undergoing pasteurization or hot fill processes. It must not be used for fatty or oily foodstuffs.



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**EU Food Law: Dual Use Additives: Statement for DARAFORM® 6411MF**

(F820)

We confirm that additives where they have a dual use as a direct food additive or are authorised as a food additive or flavouring (REGULATION (EC) No 1333/2008 and REGULATION (EC) No 1334/2008 respectively refer) are known to be present in this product as supplied by Darex Packaging Technologies.

**EU REGULATION 2023/2006: Statement for DARAFORM® 6411MF**

(F744)

EU REGULATION 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

EU Regulation 2023/2006 concerns good manufacturing practice of materials and articles intended to come into contact with food throughout the supply chain. This came into force in January 2007 and has been applied since 1st August 2008.

Darex Packaging Technologies manufactures can sealants and seaming compounds, closures and can coating products at locations in EU.

These locations employ management systems that control:

- a) Raw material specification and approval
- b) Procedures for the standardization of manufacturing processes
- c) Personnel with clearly identified responsibilities for quality assurance
- d) Quality control to ensure any deviations are captured and corrective actions are instigated
- e) Control procedures for documents that affect on product safety, compliance and quality

With specific reference to the Annex, Section 1, external coatings products are formulated so that when applied in accordance with our recommendations, none of the starting substances are expected to be transferred to the food contact surface during application.

It is the opinion of Darex Packaging Technologies that we meet the requirements of good manufacturing practice as laid out in EU Regulation 2023/2006.

**REACH - SVHC: Statement for DARAFORM® 6411MF**

(F607)

To the best of our knowledge, Darex Packaging Technologies does not intentionally use Substances of Very High Concern (SVHC) as identified in the ECHA Website "Candidate List of Substances of Very High Concern for Authorisation – dates of inclusion up to and including 15/01/2019" as additives or raw materials in the above mentioned product in concentrations exceeding 0.1% in the dried or cured product.

Notification to ECHA of articles containing Substances of Very High Concern is only required if the substance concentration exceeds 0.1%. Therefore, articles containing this product are not expected to meet this criteria.

The full list of chemicals may be found at:

<http://echa.europa.eu/web/guest/candidate-list-table>



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**REACH Status: Statement for DARAFORM® 6411MF**

(F648-2)

We can confirm that all substances that we place on the EU market as such or within our products comply with the REACH regulation.

Darex Packaging Technologies is generally a Downstream User of chemicals for its DAREX®, DARASEAL®, DARABLEND®, DARAFORM®, CELOX® and SINCERA® branded can & closure sealants and as such has been relying on our suppliers to make the necessary registrations based on the volumes placed on the market.

The REACH compliance of our suppliers is checked and the status recorded.

Based on the extensive information we have received from our suppliers and our verification of the information, finished products currently supplied to your organization will continue to be available within the EU.

We would like to point out that when this product as supplied by Darex Packaging Technologies is applied to metal cans, ends and closures, etc., the article approach of REACH becomes valid.

We would like to remind you that REACH is an ever-changing program and new information comes in continuously. If we receive any information that changes our ability to provide products to you, we will advise you and discuss alternate solutions from our product portfolio.

**Supporting data: Statement for DARAFORM® 6411MF**

(F802-3)

The attached extract from the third party laboratory certificate for this product shows the details of the overall migration into different food simulants as well as the details of the specific migration and the identity of dual use additives.

Enclosure: Supporting data taken from SQTS Examination Report dated 3 October 2014

**US FDA: Statement for DARAFORM® 6411MF**

(F841)

When properly applied and if necessary dried or cured in accordance with our application recommendations, we confirm that this product, as supplied by Darex Packaging Technologies is compliant with US FDA 21 CFR 177.1210 - Closures with sealing gaskets for food containers.

**US FDA & EU Food Law: Statement for DARAFORM® 6411MF**

(F661-1)

Please see the enclosed supporting third party laboratory certificate for this product as supplied by Darex Packaging Technologies.

Enclosure: SQTS Examination Report dated 3 October 2014

**Disclaimer:**

**The above statement(s) are based on our current knowledge and experience and on legislation in effect on the date above. This compliance statement does not warrant against modifications of this product resulting from its processing or from the addition of other products, nor against any inadequate use and/or storage of this product or the materials and articles containing it. The present statement also does not warrant compliance with legislation changed after the date above.**

**This document has been created electronically and is valid without signature.**

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