

# Food Packaging Certificate

## Declaration of Conformity (Art. 15 Regulation (EU) No 10/2011)

This Declaration does apply only to the product as packaged or delivered by BASF and is valid for product produced in Ludwigshafen/Germany only.

We hereby confirm that our plasticizer Hexamoll® DINCH is listed in

**Annex I, Table 1 of Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food** most recently amended by the Commission Regulation (EU) 2019/37 of 10 January 2019

as additive or polymer production aid. According to the regulation the following restriction applies:

Substance Name	1,2-cyclohexanedicarboxylic acid, diisononyl ester
<b>FCM-No.</b> The unique identification number of the substance in the Regulation (EU) No 10/2011	775
<b>PM-Ref No.</b> EEC packaging material reference number	45705
<b>Group Restriction No. 32: SML(T)</b> Migration limit in food or in food simulant for the respective substance group	60 mg/kg

Though no substance-specific restriction or migration limit applies, the conformity with the group restriction should be checked, especially when using Hexamoll® DINCH for materials that are intended to come into contact with fatty food.

Presuming appropriate processing, the product can be used in the countries of the European Community for the manufacture of food contact materials or articles according to

### **Article 3 of Regulation (EC) No 1935/ 2004**

*"Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC".*

For notice: Appropriate conditions have to be applied when processing the product. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be tested and ensured in each case by the person who places any finished food contact article on the market. The product must not be used in any medical device and/or pharmaceutical applications.

## **Switzerland:**

The product is listed in the Swiss Ordinance on Materials and Articles in Contact with Food, "Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen" SR 817.023.21 of 01. May 2017, Annex 10 "Lists of permitted substances for the manufacture of packaging inks", Part A.

The specific restrictions and migration limits for the listed substances are the same as laid down in the European Regulation (EU) No 10/2011 and its subsequent amendments.

## **Japan:**

Hexamoll® DINCH is approved by the Japan Hygienic PVC Association (JHPA) for use only of non-fatty food and at levels not exceeding 100phr.

## **Australia:**

The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) approved Hexamoll® DINCH for food packaging in their following assessments:

STD/1259 (2008) Use: Plastics

EX/165 (STD/1259) (2011) Use: Printing Industry

EX/170 (STD/1259) (2012) Use: Surface Coatings.

## China:

The product is listed in the National Standard of the People's Republic of China GB9685-2016 (Standard for uses of Additives in Food Contact Materials and Articles), issued Oct. 19<sup>th</sup>, 2016. The following restrictions apply:

(Isononyl) 1,2-cyclohexanedicarboxylate; 1,2-Cyclohexanedicarboxylic acid, diisononyl ester (FCA0045): SML = 60 mg/kg; SML(T) = 60 mg/kg

Application: Plastic (PE, PP, PS, AS, ABS, PA, PET, PC, PVC: dosage as necessary)  
Compliance with specific restrictions mentioned in GB 9685-2016 has to be ensured by the person who introduces food containers and packaging materials into the market.

## USA:

Hexamoll® DINCH is listed in Table D1 of the US National Sanitation Foundation Standard 61 for drinking water system components with

TAC (total allowable concentration): 5 mg/L

SPAC (single product allowable concentration): 0.5 mg/L

STEL (short-term exposure level): 5 mg/L

## Mexico:

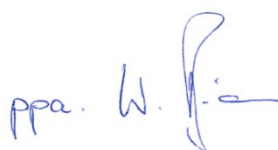
Hexamoll® DINCH is eligible for food contact applications via K&H opinion referring to EU, Health Canada and Australian NICNAS evaluation. It may be considered safe for its intended use in Mexico, provided it is used in accordance with the EU's specific migration limit (SML(T)) or used in accordance with Health Canada's no-objection letter.

## Canada:

According to the No-Objection-Letter on the use of Hexamoll® DINCH in food packaging applications by the Health Products and Food Branch (HPFB) of Health Canada, Hexamoll® DINCH may be used as a plasticizer in polyvinyl chloride (PVC) resins intended for the following applications:

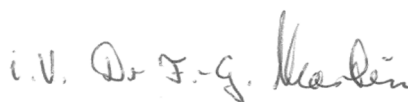
- a) In film intended to contact fatty foods (e.g. fresh meat) at a maximum level of 10%;
- b) In film intended to contact aqueous, acidic, and low alcoholic foods (e.g. fruit and vegetables) at a maximum of 35%
- c) In closure and gasket systems for containers intended to contact non-alcoholic and alcoholic (i.e. beer and wine) beverages at a maximum level of 35%

- d) In artificial corks intended to contact alcoholic beverages (i.e. wine) at a maximum of 35%
- e) In flexible tubing intended to contact non-alcoholic and alcoholic (i.e. beer and wine) beverages at a maximum level of 40%
- f) In conveyor belts intended to contact all food types at a level of 12%



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**Note:**

These statements are based on our current knowledge and experience. In view of many factors that may affect processing and application of our product, this does not relieve processors from carrying out their own investigations and tests; neither does it imply any guarantee of certain properties, nor the suitability of the product for a specific purpose. It is the responsibility of the recipient of our products to ensure that any proprietary rights and existing legislation are observed.

The data indicated above are the results of our investigations and correspond to the state-of-the-art. The data refer to the state of the laws at the date of issue. This confirmation expires after one year at the beginning of the month indicated on page 1 or in case of regulatory changes. Please ask for a new confirmation if needed. It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed. The certificate is exclusively for our customers and respective competent authorities. It is not intended for publication either in printed or electronic form (e.g. via Internet) by others. Thus, neither partial nor full publication is allowed without written permission by BASF SE.