



# FOOD CONTACT DECLARATION

Version: FCD.MB130.01.230929

**It is the responsibility of our customer to check if the materials supplied by ADC and articles made out of it are suitable for the intended use and comply with all applicable regulations and requirements.**

As a manufacturer of plastic intermediate materials, **ADC** confirms that **CALMAST MB130** has been formulated and manufactured in accordance with the relevant requirements of the following food contact recommendations or regulations:

## EUROPE

### European Union (EU)

**Regulation (EC) No 1935/2004** of the European Parliament and of the Council for the following aspects:

- **Traceability**

Systems are in place that identify suppliers and customers one step forward/one step back in the value chain.

- **Declaration of compliance/Supporting Documentation**

This product will be accompanied by a written declaration, stating it complies with the relevant applicable food contact rules. Appropriate supporting documentation is available for competent authorities on their demand to demonstrate such compliance this documentation will be renewed in case of substantial changes.

- **Good Manufacturing Practice (GMP)**

This product has been manufactured in accordance with relevant requirements of Commission Regulation 2023/2006 of 22 December 2006, on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food amended by Regulation 282/2008 of 27 March 2008.

- **Specific Measures**

All components that comprise **CALMAST MB130** are either listed or exempted from listing according to Commission Regulation (EU) No 10/2011, regulating plastic materials and

articles intended to come into contact with food, up to and including amendments Regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/988, 2019/1338, 2020/1425 and Commission Regulation (EU) No 2023/1442.

In accordance with the requirement described in Annex IV of Commission Regulation (EU) No 10/2011 to disclose adequate information about substances that are subject to restrictions and/or specifications set out in Annexes I and II to the aforementioned Regulation, We refer to the information given in the annex to this document.

### **Overall Migration Limit (OML) testing**

To determine the OML, migration experiments have been carried out using monolayer film as test specimen (100 micron, S/V ratio 6 dm<sup>2</sup>/kg) made of **CALMAST MB130**, in food simulants B, C and D2 (according to Table 1 of Annex III of Commission Regulation (EU) No 10/2011) under testing conditions covering long term storage above 6 months at room temperature and below, including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes (OM2 in table 3, Annex V of Commission Regulation (EU) No 10/2011).

### **Specific Migration Limit (SML) testing**

For substances regulated with a SML and listed in Attachment "Substances subject to restrictions or Specifications", SML migration modelling estimates following a worst-case calculation, assuming 100% migration, or migration experiments during 10 days at 60°C, using monolayer film as test specimen (100 micron, SV ration 6dm<sup>2</sup>/kg) made of **CALMAST MB130** or a comparable grade in food simulants B, C and D2 (According to Table 1 of Annex III of Commission Regulation (EU) No 10/2011), have been carried out.

### **Test Summary**

Results have shown that under mentioned conditions migration limits (overall and if applicable specific) were not exceeded.

### **Compliance work to be performed by the Raw material producer**

In accordance with the guiding principles to avoid duplication of compliance work and to conduct compliance work as early as possible in the supply chain, **ADC** has conducted hazard assessments in accordance with Article 19 of Commission Regulation (EU) No 10/2011, on standard test specimens under standardized testing conditions. Due to its role in the supply chain as a plastics intermediate materials manufacturer, **ADC** can confirm compliance to Article 3(1)a of Regulation (EC) 1935/2004, and amendments. ADC cannot assess exposure

under every actual or foreseeable condition of use of the finished plastic material or article, wholly or partly composed of **CALMAST MB130**. As a result, compliance to Articles 3(1)b and 3(1)c will have to be demonstrated by the producer of the final plastic material or article before placing it on the EU market.

However, in order to support our customers to conclude on their own compliance work required by Article 3(1)(a) of Regulation (EC) No 1935/2004, upon specific request, based on customer's exposure assessment, **ADC** may provide hazard information relevant for **CALMAST MB130**.

**Regulation 282/2008** of 27 March 2008, on recycled plastic materials and articles intended to come into contact with foods amended by Regulation 2015/1906. **ADC** does not use recycled plastic in grades product.

**Regulation 1895/2005** of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food. **ADC** does not include BADGE, BFDGE and NOGE in the composition of grade product.

**Regulation 321/2011** of 01 April 2011, amending Regulation 10/2011 on restriction of use of Bisphenol A (BPA) in plastic infant feeding bottles. **ADC** does not include Bisphenol A in the composition of this product.

### **Germany**

Recommendation III "Polyethylene" of plastics in food traffic: Recommendations of the Federal Institute for Risk Assessment (BfR) (Former BgVV)

Status: April 1, 2021

Consumer Goods Ordinance in the version published on December 23, 1997, latest relevant amendment of December 7, 2021 (BGBl. 2021, Part I, No. 82, p. 5068-5125).

### **Non EU Countries**

#### **United Kingdom**

UK statutory Instruments, 2019 No.704: *"The Materials and Article in Contact With Food (Amendment) (EU Exit) Regulations 2019"*.

The statutory instrument provides the necessary safety requirements to ensure businesses are producing safe food contact materials and articles for the UK's end users.

The policy objective of the statutory instrument is to maintain existing EU laws in the UK and fix the inoperabilities in retained direct EU legislation related to materials and articles in contact with food. It includes the following directly relevant EU regulations:

- **Regulation (EC) No. 1935/2004:** (“The Framework Regulation”) on materials and articles intended to come into contact with food.
- **Regulation (EU) No. 10/2011:** On plastic materials and articles intended to come into contact with food.
- **Regulation (EC) No. 2023/2006:** On Good Manufacturing Practice for materials and articles intended to come into contact with food.
- **Regulation (EC) No. 1895/2005:** on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- **Regulation (EU) No. 2018/213:** On the use of bisphenol A in varnishes and coatings intended to come into contact with food.

UK statutory Instrument, 2019 No.704 ensures that the retained EU law in UK domestic regulations continue to be operable after UK’s exit (a.k.a. BREXIT) from the European Union.

## **AMERICANS**

### **United States of America (USA)**

The product comprising **CALMAST MB130** is listed in the code of federal regulation (CFR), title 21, paragraph 177.1520 (olefin polymers), issued by the Food and Drug Administration (FDA).

All adjuvants are cleared according to CFR Title 21, part 178 (Indirect food additives), are generally as safe (GRAS), are prior-sanctioned food ingredients, are cleared on basis of regulations for food additives of before 1958 or are cleared via a Food Contact Notification (FCN).

Extraction experiments with 100 µm film samples made of **CALMAST MB130** or a comparable grade, have shown that the extraction limits specified in US Code of Federal Regulations (CFR), issued by the Food and Drug Administration (FDA), Title 21, paragraph 177.1520(c), item 3.2a, were not exceeded.

This material may be used in articles for packing or holding food during cooking.

That is comparable to conditions of use A-H as described in Table 2 of the Code of Federal Regulations (CFR), issued by the Food and Drug Administration (FDA), Title 21, paragraph 176.170(c). The material must of course be technically suitable for the intended use.

Status: January 10, 2023

### **MERCOSUR (Argentina, Brazil, Paraguay, Uruguay, Venezuela)**

Monomers in **CALMAST MB130** are listed on Resolution GMC No. 02/12 "*Mercosur Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the production of plastic containers and equipment in contact with food*" and amendments up to and including Resolution GMC No 19/21.

### **Middle East**

#### **GCC (Bahrein, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates)**

Monomers and additives in **CALMAST MB130** are listed as authorised for materials in Table 1 of Gulf Technical Regulation GSO 1863:2021 (Cancelling and replacing Gulf Technical Regulation GSO 1863:2013)

It has to be noted that Gulf Technical Regulations GSO 2231:2012 (General Requirements For the Materials Intend To Come Into Contact With Food), GSO 839:2021 (Food Packages - Part 1: General Requirements) and GSO 1863:2021 (Food packages - Part 2: Plastic package - General Requirements) typically set general (technical performance) requirements for materials and articles, that in their finished state as final article, are intended to or reasonably expected to contact food.

**ADC** materials are plastic intermediate materials to be converted into final articles. **ADC** does not produce final articles. It is the responsibility of the producer of the final article to check if the materials supplied by **ADC** and final articles made out of it are suitable for the intended use and comply with all applicable regulations and requirements.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned standard, please refer to the information given at the end of this document.

### **ASIA PACIFIC**

#### **The People's Republic of China (PRC)**

##### **GB4806.1-2016**

PRC National Standard GB4806.1-2016 "*General Safety requirements for food contact materials and articles*", as applicable to plastic basic resins, for the following aspects:

- **Traceability**

Systems are in place that identify suppliers and customers one step forward/one step back in the value chain.

- **Declaration of compliance/Supporting Documentation**

This product will be accompanied by a written declaration, stating it complies with the relevant applicable Chinese food contact rules. Appropriate supporting documentation is available for competent authorities on their demand to demonstrate such compliance this documentation will be renewed in case of substantial changes.

- **Specific Measures**

All components that comprise **CALMAST MB130** are either listed or exempted from listing according to PRC national Standards GB4806.6-2016 and GB9685-2016, regulating plastic materials and articles intended to come into contact with foodstuffs.

- **Good Manufacturing Practice (GMP)**

This product has been manufactured outside the People's Republic of China, but in accordance with relevant requirements of Commission Regulation 2023/2006 of 22 December 2006, on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food. These requirements are similar to the requirements of PRC National Standard GB 31603-2015 (China GMP standard).

### **Malaysia**

Monomers and additives in **CALMAST MB130** are listed as authorized on Annex A and B, respectively, of Malaysian standard MS 2234:2009 on Plastics materials and articles intended to come into contact with food.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned standard, please refer to the information given at the end of this document.

### **The Republic of India**

**CALMAST MB130** comprises a basic resin that is listed in Indian Standard IS 16738:2018 (*Positive List of Constituents of Polyethylene and Polypropylene in Contact with Foodstuffs, Pharmaceuticals and Drinking water*), superseding IS 10141:2001 and IS 10909:2001.

### **GENERAL INFORMATION**

We request you to use information contained in this document for compliance purposes only.

We wish to stress that test results referred to in this declaration are performed on standard test specimens under standardized testing conditions. These results may differ significantly from the performance of the finished plastic material or article under actual and foreseeable conditions of use and may not be used to demonstrate regulatory compliance of finished plastic materials or articles.

**ADC** has no control over finished plastic materials or articles nor over their manufacturing, processing and use conditions and can never accept any responsibility for compliance of these finished plastic materials or articles. **ADC** cannot be held responsible for changes that may result from further processing of its product by other parties in the supply chain. It is the responsibility of downstream users to check compliance in the end application through proper end use testing based on the information provided by supply chain.

This declaration is restricted to **CALMAST MB130** as it leaves the production facilities. This declaration does not cover:

- Any substance subsequently added by end users.
- Poor material or finished article due to inexpert manufacture by downstream users.
- Any negative influence of the finished article on the organoleptic properties of the packaged food.

If you have any further questions, or require any additional information on the above, Please contact for me. Thank you.

### **Attachment**

We request you to use the identity and information of disclosed substance(s) for compliance purposes only.

### **SUBSTANCES SUBJECT TO RESTRICTIONS OR SPECIFICATIONS**

References to substance identifications in this section come from Annex I of Regulation (EU) 10/2011 (FCM substance No), US FDA code of Federal Regulations (CFR), Title 21.

Substances that are intentionally used in or added to **CALMAST MB130** comply with the compositional requirements set out in Chapter II of EU Commission Regulation (EU) 10/2011, and amendments. **CALMAST MB130** does not release substances (if present) in quantities exceeding the specific migration limits expressed in mg/kg food or simulant listed in Table 1 of Annex II of EU Commission Regulation (EU) 10/2011, and amendments.

Monomers: No monomers subject to restriction are used

Additives/other:

- Acid Stearic (Cas no 0000057-11-4) unlimited use.
- Polyethylene Wax (Cas no 0009002-88-4) unlimited use.
- Zinc compound (s), Which is/are regulated with a specific migration limit of 25 mg/kg food (expressed as Zic) in China and India, except in the EU where this limit is 5 mg/kg food.

Present dual use additives:

- None

Primary Aromatic Amines (PAA) including those listed in Appendix 8 to entry 43 of Annex XVII to Regulation (EC) No 1907/2006 (EU REACH), and amendments.

The absence of the substances has not been checked by test.

Base upon information received from raw material suppliers or manufacturers and/or knowledge of the presence of genotoxic substances, we can inform you that **CALMAST MB130** does not contain intentionally added genotoxic substances, we can inform you that **CALMAST MB130** does not contain intentionally added genotoxic substances, originating from the used raw materials in the manufacturing process or degradation products thereof, that foreseeably give rise to a migration from the final material > 0.00015 mg/kg food simulant, determined by a worst-case calculation (assuming 100% migration), or migration modeling using an EU-recognized mathematic migration model, or migration experiments during 10 days at 60°C using standard test specimens, an SV ratio of 6 dm<sup>2</sup>/kg and standard food simulants (according to Table 1 of Annex III of Commission Regulation (EU) No 10/2021).