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Declaration, July 2021

Exolon® FG clear 098 Exolon® FG clear 099 Statement on Food Contact Use

This statement is valid for the following products:

- Exolon® FG clear 098
- Exolon® FG clear 099

Exolon® FG clear 098 and 099 may be used for the manufacture of articles intended for food contact as outlined below and belongs to the group of polycarbonate plastics.

Europa – regulation (EC) 1935/2004

This statement has the purpose of a declaration of compliance as required by Regulation (EC) 1935/2004.

Exolon® FG clear 098 and 099 are manufactured applying rules on Good Manufacturing Practice (GMP) which are considered appropriate for plastic raw materials as required by Regulations (EC) 1935/2004 and (EC) 2023/2006. This includes the use of procedures to cover traceability from the incoming starting materials to the outgoing food contact material.

Commission Regulation (EU) 10/2011

Exolon® FG clear 098 and 099 are manufactured only with monomers and additives that are authorized under the Commission Regulation (EU) No. 10/2011 of 14 January 2011 on "plastic materials and articles intended to come into contact with food" and its amendments. All monomers and additives used for the manufacture of Exolon® FG clear 098 and 099 are listed in Annex I of the Commission Regulation (EU) No. 10/2011 and its amendments such as 2016/1416, 2018/79, 2018/213, 2018/831, 2019/37 and 2020/1245.

The manner in which you use and the purpose to which you put and utilize our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products, technical assistance, information and recommendations to determine to your own satisfaction whether our products, technical assistance and information are suitable for your intended uses and applications. This application-specific analysis must at least include testing to determine suitability from a technical as well as health, safety, and environmental standpoint. Such testing has not necessarily been done by Exolon Group. Unless we otherwise agree in writing, all products are sold strictly pursuant to the terms of our standard conditions of sale which are available upon request. All information and technical assistance is given without warranty or guarantee and is subject to change without notice. It is expressly understood and agreed that you assume and hereby expressly release us from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance, and information. Any statement or recommendation not contained herein is unauthorized and shall not bind us. Nothing herein shall be construed as a recommendation to use any product in conflict with any claim of any patent relative to any material or its use. No license is implied or in fact granted under the claims of any patent.

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Specific limits

The table below provides information on specific restrictions which must be observed according to Commission Regulation (EU) No. 10/2011 and its amendments:

CAS number	Name	Restrictions SML= specific migration limit in food or simulant: QM = max. permitted quantity of residual in plastic
80-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 0.05 mg/kg Not to be used for the manufacture of polycarbonate infant feeding bottles. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children. ¹⁾
102-09-0	Diphenyl carbonate	SML = 0.05 mg/kg
75-44-5	Carbonyl chloride	QM = 1 mg/kg in final product
108-95-2	Phenol	SML = 3 mg/kg

1) COMMISSION REGULATION (EU) 2018/213 of 12 February 2018: in force since 6 March 2018, applicable as of 6 September 2018. Plastic materials and articles that were lawfully placed on the market before 6 September 2018 may remain on the market until exhaustion of stocks (previous provision according to Commission Regulation (EU) No. 10/2011: SML = 0.6 mg/kg, not to be used for the manufacture of polycarbonate infant feeding bottles).

Use conditions

The above mentioned limits have been met in exemplary investigations on virgin material representing the composition of Exolon FG clear 098 and 099. Both overall and specific migration were assessed for a surface/volume ratio of 6 dm²/kg food. Temperature, time and simulants used for the assessments are given below:

- Overall migration OM 5 (2 h at 100°C or Reflux) followed by OM2 (10 days at 40°C) in simulants B and D1
- Overall migration OM3 (2 h at 70°C) in simulants A and D2
- Specific migration: 10 days at 60°C in simulants B and D1
- Specific migration: 1 hour at 40°C in simulants D2

This declaration of compliance is only valid for the temperature/time as described.

It is the responsibility of the user of our products, who manufactures materials or articles intended for food contact or brings them into contact with food, to assure their compliance with limits and other provisions set by the applicable regulations.

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Dual Use additives

No dual use substances according to regulations (EC) No. 1333/2008 and 1334/2008 and their amendments have been used as additives.

Assessment

A risk assessment was performed according to Article 19, the Commission Regulation (EU) No. 10/2011, for two cases:

General: foods covered by simulants A and D1; 10 days 60°C; single and repeated use

Specific: food simulant D2; 1 h at 40°C; repeated use only; 6750 kg chocolate contacting per kg plastic mould over the use period).

It is the responsibility of the user of our products, who manufactures materials or articles intended for food

contact or brings them into contact with food, to perform risk assessment according to Article 19 of Commission Regulation (EU) No. 10/2011 for their own specific use conditions.

Germany

BfR-Recommendations on Food Contact Materials
(*Bundesinstitut für Risikobewertung*)/Federal Institute for Risk Assessment)

The colorants used comply with the requirements of Recommendation IX "Colorants for plastics and other polymers used in commodities", issued by the Federal Institute for Risk Assessment (BfR), status: 2015-02-01.

France

From 1st January 2015, Exolon® FG clear 098 and 099 are not permitted for any food contact applications in France based on law No. 2012-1442 of 24 December 2012.

According to the implementation note of the bisphenol A law by the French DGCCRF (Direction générale de la concurrence, de la consommation et de la répression des fraudes) (<https://www.economie.gouv.fr/dgccrf/mise-en-oeuvre-loi-bisphenol-a-bpa>), law No. 2012-1442 does not apply to industrial materials and equipment used in the production, processing, storage or transport of foodstuffs such as fixed or mobile tanks, reservoirs and tanks, silos, pipes and hoses, industrial production tools such as chocolate moulds solidly integrated into production machinery for large volume series, industrial systems with solidly integrated fittings incorporating pastry used by food companies.

However, it applies to utensils and containers (e.g. moulds, pans and pastry tins etc.) for sale to consumers or for sale in mixed consumer/professional sectors (such as pastry chefs, restaurateurs).

Belgium

Exolon® FG clear 098 and 099 are not permitted for food contact articles intended for children up to the age of 3 according to the law of 24th January 1977 on the protection of consumer health regarding food contact articles as amended in September 2012.

Denmark

Exolon® FG clear 098 and 099 are not permitted for food contact articles intended for children up to the age of 3 according to Decree on infant formula and formulas for infants and toddlers (No. 1504 of December 13, 2007) and Decree on processed baby foods for infants and toddlers (No. 355 of June 17, 1998) as amended in July 2010.

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USA

Exolon® FG clear 098 and 099 are in chemical compliance with FDA regulation 21 CFR § 177.1580 (Polycarbonate resins) and with applicable FDA regulations for food-contact applications under FDA Conditions of Use B through H, subject to the limitations of this regulation and any other applicable regulations. Specific limitations to products containing 2,2-Bis(4-hydroxyphenyl)propane (Bisphenol A or "BPA") may apply under US Federal and/or State law.

China

The use of products containing 2,2-Bis (4-hydroxyphenyl)propane (Bisphenol A or "BPA") is restricted for infant feeding bottles according to Announcement 2011/15 of the Ministry of Health.

One of the colorants used for Exolon® FG clear 099 is not yet authorized for polycarbonates by the Chinese standard GB 9685-2008 ("Hygienic standards for uses of additives in food containers and packaging materials") and its amendments (status: May 2013). However from a global scientific point of view, there should not be any doubt that the colorant is suitable for said application, as it complies with most relevant regulations in the international context (Council of Europe Resolution AP(89), BfR Recommendation IX, French Positive List (Circulaire 176), FDA Regulation 21 CFR § 170.3(e)(1), JHOSPA Positive List 2-32 Dyestuffs (04.2009)).

An application for approval of the colorant is under preparation which will re-establish the authorization of the product for food contact use.

BSE statement (Bovine Spongiform Encephalitis)/ Renewable Raw Materials

All chemicals used for the production are of petrochemical/inorganic origin. Therefore we are convinced that there is no risk of contamination with BSE/TSE germs.

Remark

This declaration only applies to products made by Exolon Group.

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The logo for Exolon, featuring the word "exolon" in a bold, red, sans-serif font, with a registered trademark symbol (®) to the upper right.