Declaration of Compliance

for products made of plastic intended to come into contact with foodstuffs

Publisher, Manufacturer:

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Product

Lamigamid® 312

We herewith confirm that the semi-finished product made from the material mentioned above is in compliance with the requirements of the following regulations:

- (EC) No 1935/2004 of the European Parliament and the Council dated 27th October 2004 applicable for materials and goods destined to come into contact with foodstuffs and for revocation of the directives 80/590/EEC and 89/109/EEC, Gazette of the European Communities L 338/4 dated 13th November 2004, last amendment by the Article 5 of Regulation (EU) 2019/1381 of 20th June 2019, Gazette of the European Communities L 231/1 of 06th September 2019, Article 3, paragraph 1 a) and b)
- Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFGB) in the version of the notification of 15th September 2021 (BGBl. Ip. 4253), last amendment by article 7 of the Directive of 27th September 2021 (BGBl. P. 4530), §§ 30 and 31

Furthermore, the product meets the requirements of

- (EC) No 10/2011 of the Commission dated 14th January 2011 on plastic materials and articles to come into contact with food, Gazette of the European Communities L 21/1 dated 15th January 2011, last amendments by Commission Regulations (EU) No 2020/1245 of 2 September 2020, Official Journal of the European Union L 288/1 of 03.09.2020

regarding the composition and the migration behaviour.

The manufacturing of the product mentioned above is carried out according to the method „Good Manufacturing Practice“ (GMP), corresponding to the regulation (EC) No 2023/2006 of December 2006 applicable for the good manufacturing practice for materials and goods destined to come into contact with foodstuffs. According to the regulation (EC) No 1935/2004, the traceability of our products is guaranteed at all levels and is carried out by means of the production number inscribed on the product label or the accompanying documents.

Testing conditions for migration tests based on the application

The product was tested according to the methods for “examination of utensils“ by means of several samples, according to the regulation B 80.30, 1 to 3 (EC) of the Official List of testing procedures according to § 64 LFBG (Germany), as well as the series of standards EN 1186, EN 13130 and CEN/TS 14234 “materials and goods in contact with foodstuffs – plastics“.

According to the general rules for migration tests, the total migration and the specific migrations of individual substances were determined by using food simulants and pre-defined testing conditions (time/temperature). The overall migration as well as the specific migration does not exceed the legal limits set out in directive (EC) No 10/2011 when used as specified in table 1.

Table 1 - Determination of migration behavior

Testing simulant	Testing conditions	Intended contact with foodstuffs
10 Vol. % ethanol	40°C, 5 min	Single and repeated contact with type of foods displayed by simulants A, B and D2 according to EU 10/2011
3 weight % acetic acid	40°C, 5 min	
95 Vol. % ethanol (substitution for fat)	40°C, 5 min	

Ratio of the surface in contact with the foodstuff to volume (S/V), used to determine the compliance of the material:

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Information on substances used or their degradation products for which Annexes I and II of Regulation EU 10/2011 contain restrictions and / or specifications

CAS Name	Restrictions
caprolactam | Additive | Ref. No. 14200 / 41840 | CAS No. 0000105-60-2	SML(T) = 15 mg/kg

OML = total migration (OML) <10mg / dm^2
SML = specific migration limit in food or in food simulant
SML(T) = Total Specific Migration Limit
QMA = max. permitted quantity in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs.

Dual Use

The following substances, which are also approved as food additives („Dual use“), may be contained in the product mentioned above (EC directives 89/107/EEC, 95/2/EC):

CAS Name	Restrictions
	-

Does not contain additives that are simultaneously approved as food additives by Regulation (EC) No. 1333/2008 or as flavorings by Regulation (EC) No. 1331/2008

(as far as information concerning this point is included in the conformity documents made available by the raw material producer.)

NIAS (non-intentional added substances)

As part of the conformity assessment, studies on non-intentional added substances (NIAS) were performed by means of GC-MS screenings on representative selected test samples.

No impurities or side reaction or degradation products (NIAS) could be identified.

Functional Barrier

Use of a functional barrier acc. Regulation (EU) No 10/2011 Article 3: None

Result

The quality Lamigamid® 312 can be used safely for the manufacture of finished products for companies which are preparing and processing foodstuffs. The finished products may stand in direct contact with all types of food as far the quality Lamigamid® 312 is concerned.

It is important that the above-mentioned contact times and temperatures are not exceeded regarding the Regulation (EU) No 10/2011.

General Information

This declaration serves as a supporting document for the downstream user. Our semi-finished materials or cuts from these semi-finished materials are products from intermediate stages of production in accordance with Regulation (EU) 10/2011, Article 15 and are not consumer goods in the sense of the Bedarfsgegenständeverordnung (§ 2) and the Lebensmittel- und Futtermittelgesetzbuchs (§ 2 Abs. 6 Satz 1 Nr. 1), as well as Regulation EC/1935/2004, Article 1, Para. 2.

The formulations of our materials listed in the declarations of conformity have been subjected to extensive migration tests with various simulants in accordance with EU 10/2011 at an independent accredited institute. The tests were carried out on mechanically processed samples of our semi-finished products.
Furthermore, it has been assured that generally only such raw materials are used for the material where the appropriate verifications of suitability (supporting documents) have been provided by the raw material supplier or the raw material supplier discloses its ingredients to a suitable third party (testing institute/laboratory) by means of a confidentiality agreement.

The material is basically suitable for use in contact with food under the aforementioned conditions. However, since we do not know the conditions of use of the finished articles, it remains the responsibility of the customer to determine the suitability of the plastic articles (consumer goods) produced from or with our products for their intended use or rather under the respective conditions of use (contact time, contact temperature for the respective type of foodstuff). In addition to the general suitability for use of the material (e.g. chemical resistance to the cleaning agent used), such responsibility also includes observation of the migration limits in the event the actual contact conditions exceed or deviate from the "intended food contact" laid down in our declaration of conformity.

The aforementioned products are not suitable for medical or dental applications.

Organoleptic Testing:

In the case of coloured grades (all materials not of natural colour), determination of colour fastness was carried out in accordance with the method for testing the colour fastness of articles intended to come into contact with foodstuffs that are made of coloured plastic and other polymers, 24th Communication on the testing of plastics: Bundesgesundheitsblatt 15, 285 (1972). Destilled water, 2% acetic acid, 10% ethanol and peanut oil as substitute for fat were used as test stimulants. Result: the colouring is colourfast when in contact with all test stimulants.

Odor and taste tests were omitted, because due to the almost unlimited possibility of combining foods and contact conditions, a representative selection of suitable test foods and associated contact parameters (temperature/time) cannot be practically guaranteed at our stage of the process chain.

On request of the customer our semi-finished products can be finished in our in-house cutting department. This declaration covers semi-finished products in the above-mentioned quality that can be cut to the desired size by means of sawing and/or planing (without the use of cooling lubricants). Cooling lubricant is used during grinding.

We refer to these guidelines and regulations and its changes that were valid on the date of issue. All information corresponds to the current technical and scientific level of our knowledge. This declaration is reevaluated in the event of relevant changes to guidelines, ordinances, recipes and processes. Our recommendations do not release the user from the obligation to check our products with regard to their suitability for their processes and purposes, as well as to examine the possibility of impairing the rights of third parties, if necessary.

Liability claims against the issuer of this declaration of conformity related to damage of a material, immaterial or ideal nature and caused by the usage or non-usage of the information offered or by the usage of defective and/or incomplete information are excluded on principle.

All information contained in this document is provided in good faith and is based on sources believed to be reliable at the time of publication of this document. In the event of changes, for example due to legislation, manufacturing-related changes, or new scientific findings, new statements will be published on our website https://www.roechling.com/industrial/materials/thermoplastics/engineering-plastics/pa/pa-6-g/lamigamid-312-709657. Previous declarations will become invalid as a result. This declaration expired 12 months after the date of issue (Print). It is the sole responsibility of our customer to ensure that the laws and regulations necessary for their intended use are complied with. Therefore, if necessary, please request a new confirmation or download it from our website https://www.roechling.com/industrial/materials/thermoplastics/engineering-plastics/pa/pa-6-g/lamigamid-312-709657.

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