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Food contact regulations compliance

This statement contains the declarations of compliance for food contact regulations throughout the world and is valid for the following products produced at TotalEnergies Corbion Ltd. (Thailand):

- Luminy® PLA L105
- Luminy® PLA L130
- Luminy® PLA L175
- Luminy® PLA LX530
- Luminy® PLA LX575
- Luminy® PLA LX175
- Luminy® PLA LX930
- Luminy® PLA LX975

This statement covers Luminy® PLA grades with the suffix BMB and RMB, including all numerical values behind this suffix.¹

This statement does not cover converters and/or final product manufacturers in case of:

- modification of our product by any addition of any other product to it.
- modification of the product resulting from processing of the product.
- inadequate use and/or storage of the material and of the finished article.

Europe

The above-mentioned products [hereinafter called Luminy® PLA] as supplied by TotalEnergies Corbion, have been evaluated and were found to be suitable for use in food contact applications in the European Union.

The evaluation was in line with the requirements of Regulation (EC) No 1935/2004 of 27 October 2004 and Regulation (EC) No 10/2011, as amended by 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338, 2020/1245, 2023/1442, 2023/1627, and 2024/3190 applying to all EU member states, and the Commodity Act Packaging and Food Utensils Regulations of the Netherlands and its amendments [Hereinafter called 'Regulations'].

Luminy® PLA is produced using ingredients listed in Table 1 of Annex 1 of the Plastics Regulation. There are no specific migration limits (SML), or total specific migration limits (SML(T)) listed under Table 1 of Annex 1 for these ingredients.

Although Luminy® PLA is not subject to any SML or SML(T), EC 10/2011 specifies that plastic materials and articles to come into contact with food have to meet an overall migration limit (OML) of 10 mg/dm². Luminy® PLA complies with this OML based on testing performed by TotalEnergies Corbion PLA. Suitability of use of Luminy® PLA has been shown for all food types under condition OM6 (and below).

The finished material or article manufacturer is responsible for compliance with the OML of the finished product in which Luminy® PLA is used.

Regarding lactic acid, it should be taken into account that it is to be considered as a dual use substance according to Regulation 10/2011, since lactic acid is approved as a food additive (additive number E270). For lactic acid, there are no SML or SML(T) set in Regulation 10/2011.

¹RMB (Recycled Mass Balance) grades are PLA with allocated recycled content according to the principles of mass balance. BMB (Bonsucro Mass Balance) grades are PLA grades where the principles of mass balance have been applied with respect to Bonsucro chain-of-custody certification.

Luminy® PLA complies with EU Directive 94/62/EC of 20 December 1994 on packaging and packaging waste heavy metal content as described in Article 11.

Luminy® PLA is manufactured, processed and distributed according to EC 2023/2006 regarding Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food.

It is the responsibility of the manufacturer of the final product, which is intended as a food contact product, to determine that the use of the product is safe and also suitable for the intended application. While it is TotalEnergies Corbion's conclusion that the Luminy® PLA is permitted, it is the final product which must meet the given regulations and the manufacturer should take responsibility to check if the final product is in compliance with the regulations.

*TotalEnergies Corbion has applied the clause of non-disclosed substances as described in section 4.3.1 of the Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain. Migration testing in food simulants A, B and D2 at test conditions of 10 days and 60°C confirmed one tenth of the restriction cannot be exceeded for Luminy® PLA up to a thickness of 0.5 mm. In case Luminy® PLA is used at a higher thickness, it could be required to perform additional compliance work. In that case please contact your local sales representative.

Switzerland

Luminy® PLA, as supplied by TotalEnergies Corbion, has been evaluated and was found to be suitable for use in food contact applications in Switzerland.

The evaluation was in line with the requirements of Swiss Ordinance SR 817.023.21 that was originally published on 16 December 2016 and updated on 1 February 2024.

Luminy® PLA is produced using ingredients listed in Table 1 of Annex 2 and is compliant with Article 11 of the Swiss Ordinance. No specific migration limits (SML) or total specific migration limits (SML(T)) apply for these ingredients.

Although Luminy® PLA is not subject to any SML or SML(T), SR 817.023.21 specifies that plastic materials and articles to come into contact with food have to meet an overall migration limit (OML) of 10 mg/dm². Luminy® PLA complies with this OML based on testing performed by TotalEnergies Corbion. Suitability of use of Luminy® PLA has been shown for all food types under condition OM6 (and below). The finished material or article manufacturer is responsible for compliance with the OML of the finished product in which Luminy® PLA is used.

It is the responsibility of the manufacturer of the final product, which is intended as a food contact product, to determine that the use of the product is safe and also suitable for the intended application. While it is TotalEnergies Corbion's conclusion that the Luminy® PLA is permitted, it is the final product which must meet the given regulations and the manufacturer should take responsibility to check if the final product is in compliance with the regulations.

United Kingdom

Luminy® PLA as supplied by TotalEnergies Corbion, has been evaluated and was found to be suitable for use in food contact applications in the United Kingdom.

In fact, plastic or regenerated cellulose film additives that were authorized by the *European Commission (EC)* before January 1, 2021, will not need to be reauthorized by the UK authorities to be placed on the market in GB.

United States of America

Luminy® PLA as supplied by Total Corbion PLA, has been evaluated and was found to be suitable for use in food contact applications in the United States of America. On 30 November 2018, FCN 001926 as applied for by TotalEnergies Corbion to the FDA became effective. It is included in the list of effective notifications for FCNs on the website of the FDA at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/default.htm>

The evaluation performed was in line with the requirements of Section 201(s) and Section 409 of the Federal, Drug and Cosmetic Act, and Parts 182, 184 and 186 of the Food Additive Regulations, and is in line with the July 2021 Guidance by the FDA on 'Use of Recycled Plastics in Food Packaging: Chemistry Considerations'.

Luminy® PLA is not intended to be used in medical devices.

Luminy® PLA neat resin is approved for all food types for single use and repeat use articles and conditions of use B through H:

B. Boiling water sterilized

C. Hot filled or pasteurized above 150 deg. F.

D. Hot filled or pasteurized below 150 deg. F.

- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use: 1. Aqueous or oil-in-water emulsion of high- or low-fat. 2. Aqueous, high- or low-free oil or fat.

Luminy® PLA is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

It is the responsibility of the manufacturer of the final product, which is intended as a food contact product, to determine that the use of the product is safe and also suitable for the intended application. While it is TotalEnergies Corbion's conclusion that the Luminy® PLA is permitted, it is the final product which must meet the given regulations and the manufacturer should take responsibility to check if the final product is in compliance with the regulations.

China

With this letter we provide assurance that Luminy® PLA as supplied by TotalEnergies Corbion, have been evaluated and were found to be suitable for use in the food contact applications in China. Our assessment of compliance is given per relevant regulation topic.

General safety regulations and Good manufacturing practice

Luminy® PLA is manufactured, processed and distributed according to the principles of Good Manufacturing Practice (GMP) and are compliant with GB 4806.1-2016 regarding General Safety Requirements for Food contact materials and articles and GB 31603-2015 regarding General hygiene standards on manufacturing food contact materials and articles.

Regulations covering specific materials and articles

Luminy® PLA consists of Polylactic acid (PLA), which is included on the Allowable Plastic Resins list of GB 4806.7-2023 regarding National Food Safety Standard Food Contact Plastic products and articles. PLA is listed under number 86 and CAS number 9051-89-2 for use temperatures up until 100°C and no SML/QM or SML(T) applies.

Regulations covering additives used in food contact materials

Luminy® PLA is compliant with GB 9685-2016 regarding National standards of food safety on uses of additives in food contact materials and their products. Luminy® PLA is produced using only additives that are allowed for PLA in Table A1 (Food contact plastic materials and their products – allowable additives with their use requirements) with no SML/QM/SML(T) or maximum dosage level. TotalEnergies Corbion strives to minimize the additive loading and to only add appropriately to the production demand.

Compliance OML/SML test methods

Although Luminy® PLA is not subject to any SML/QM or SML(T), GB 4806.7-2023 regarding National food safety standard specifies that plastic materials and articles to come into contact with food have to meet an overall migration limit (OML) of 10 mg/dm². Based on testing that TotalEnergies Corbion has performed, Luminy® PLA is suitable for use with all food types for long term storage at room temperature including heating up to 70°C for 2 hours or heating up to 100°C for up to 15 minutes. The finished material or article manufacturer is responsible for compliance with the OML of the finished product in which Luminy® PLA is used.

Final product manufacturer responsibility

It is the responsibility of the manufacturer of the final product, which is intended as a food contact product, to determine that the use of the product is safe and also suitable for the intended application. While it is TotalEnergies Corbion's conclusion that Luminy® PLA is permitted, it is the final product which must meet the given regulations and the manufacturer should take responsibility to check if the final product is in compliance with the regulations.

Japan

Luminy® PLA, as supplied by TotalEnergies Corbion, has been evaluated and was found to be suitable for use in food contact applications in Japan.

The evaluation was in line with the requirements of the revised Food sanitation law of the Ministry of Health and Welfare Notification No. 370 and the related positive lists, which came into effect on June 1st, 2020.

Luminy® PLA is included on the positive list with reference number 1137 and 1138. When using Luminy® PLA for food contact applications in Japan, the applicable limits as described in the regulations need to be adhered to.

It is the responsibility of the manufacturer of the final product, which is intended as a food contact product, to determine that the use of the product is safe and also suitable for the intended application. While it is TotalEnergies Corbion's conclusion that the Luminy® PLA is permitted, it is the final product which must meet the given regulations and the manufacturer should take responsibility to check if the final product is in compliance with the regulations.

MERCOSUR

Luminy® PLA as supplied by TotalEnergies Corbion has been evaluated and was found to be suitable for use in food contact applications in the MERCOSUR region.

Food contact plastics are governed by GMC Resolution Numbers 32/07 (positive list of additives), 02/12 (positive list of monomers and polymers), 56/92 (general provisions and overall migration limits for plastics), and 32/10 (framework test conditions).

Luminy® PLA contains only monomers and/or polymers included in the 'List of monomers and other authorized starting substances' of Annex 1 of MERCOSUR GMC RES. No. 02/12 amended by GMC RES No 19/21.

Luminy® PLA contains only additives included in the 'Positive list of additives to be used in packaging in contact with food' of Annex 1 of MERCOSUR GMC RES. 39/19 which has replaced MERCOSUR GMC RES. No. 32/07.

Luminy® PLA is manufactured, processed and distributed according to the principles of Good Manufacturing Practice (GMP) and is compliant with the relevant requirements of MERCOSUR GMC RES. No. 03/92 on the General Criteria of Packaging and Food Equipment in Contact with Foods.

Luminy® PLA is compliant with GMC RES No 56/92 amended by GMC RES No 20/21 on general provisions for plastics.

Based on testing that TotalEnergies Corbion has performed, Luminy® PLA is suitable for use with all food types and is meeting the OML requirements of 60 mg/kg.

The finished material or article manufacturer is responsible for compliance with the OML of the finished product in which Luminy® PLA is used.

Rest of world

For compliance with food contact regulations in the rest of the world, please contact your local account manager or send an email to pla@totalenergies-corbion.com.

Maelenn Ravard

Regulatory and Sustainability manager

