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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® PDLA D070
- Luminy® PDLA D120

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® PDLA] as supplied by TotalEnergies Corbion, have been evaluated and were found to be suitable for use up to 7% in the final product 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, 2024/3190, 2025/351 and 2026/245 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® PDLA production intentionally uses substances 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® PDLA 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® PDLA complies with this OML based on testing performed by TotalEnergies Corbion PDLA. Suitability of use of Luminy® PDLA as a nucleating agent up to 7% 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® PDLA is used.

Luminy® PDLA complies with the requirements of (EC) No 2024/3190 amended by 2026/250. In fact, in the formulation of Luminy® PDLA products, there is no intentional use of *bisphenol A and all bisphenols and bisphenol derivatives that fall within the scope of Regulation (EC) 2024/3190*.

For the compliance of the product, NIAS (Non intentionally added substances) risk assessment was also conducted on Luminy® PDLA. Based on article 6(4) of Regulation EC 10/2011 NIAS do not need to be listed in the Union list but the risk assessment need to show a compliance with article 3 of the framework regulation EC 1935/2004. The NIAS definition is based on article 3(9) of

EC 10/2011. According to Article 3a of the Plastics Regulation (EC10/2011), as amended by the 19th Amendment (EC2025/351), the high degree of purity of a substance used in the manufacture of plastic materials and articles can be demonstrated if the substance only contains a minor amount of non-intentionally added substances (NIAS), that individually fulfil one of the following conditions:

- (i) they comply with the specifications or restrictions specified in the authorisation of the substance in Table 1 of Annex I, if any;
- (ii) they have been subject to a risk assessment in accordance with Article 19 and considered compliant;
- (iii) they have been subject to a toxicological assessment in accordance with the relevant guidance adopted by the Authority, which concludes that genotoxicity is ruled out, and that, on the basis of documented analysis concerning their foreseeable use, characteristics and fate during subsequent manufacturing stages, it can be reasonably assumed that none of the substances will be present in the final plastic material or article at a level that could give rise to a migration such as to their individual presence in food exceeding 0,05 mg/kg.
- (iv) they have not been subject to an assessment specified in points (ii) or (iii), but to a risk assessment which concludes, on the basis of documented analysis concerning their foreseeable use, characteristics and fate during subsequent manufacturing stages, that it can be reasonably assumed that they cannot be present in the final plastic material or article at a level that could give rise to a migration into food such as to their individual presence in food exceeding 0,00015 mg/kg.

Based on the above information, Luminy® PDLA NIAS assessment showed that when used in food contact applications at a concentration up to 7% of the final product, no NIAS present a safety risk at use.

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.

Luminy® PDLA 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® PDLA 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® PDLA up to a thickness of 0.5 mm.*

Switzerland

Luminy® PDLA, as supplied by TotalEnergies Corbion, has been evaluated and was found to be suitable for use in food contact applications up to 7% in the final product in Switzerland.

The evaluation was in line with the requirements of Swiss Ordinance SR 817.023.21 and its amendments that was originally published on 16th December 2016 and last amended by RO 2026/374. Luminy® PDLA 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® PDLA 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® PDLA used up to 7% in the final product complies with this OML based on testing performed by TotalEnergies Corbion. Suitability of use of Luminy® PDLA 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® PDLA 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® PDLA is permitted up to 7% in the final product, 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® PDLA as supplied by TotalEnergies Corbion, has been evaluated and was found to be suitable for use up to 7% 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.

China

With this letter we provide assurance that Luminy® PDLA as supplied by TotalEnergies Corbion, have been evaluated and were found to be suitable for use up to 7% in the final product 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® PDLA 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® PDLA 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 122 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® PDLA is compliant with GB 9685-2016 regarding National standards of food safety on uses of additives in food contact materials and their products. Luminy® PDLA 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® PDLA 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® PDLA is suitable for use up to 7% of the final product 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® PDLA 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® PDLA 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® PDLA, as supplied by TotalEnergies Corbion, has been evaluated and was found to be suitable for use in food contact applications in Japan up to 7% in the final product.

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, and its revision which came into effect on June 1st, 2025.

The new positive list applicable from 1st June 2025 refers to PDLA through its monomer lactic acid under the reference number 12-117.

When using Luminy® PDLA for food contact applications in Japan, the applicable limits as described in the regulations need to be adhered to.

The new positive list indicates that PLA products with D-Lactide content higher than 6% (covering Luminy® PDLA) should not be used for applications at temperatures higher than 40°C except for short exposure times including 2 hours at maximum 66°C and 30 minutes at maximum 100°C.

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® PDLA is permitted up to 7%, 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® PDLA as supplied by TotalEnergies Corbion has been evaluated and was found to be suitable for use up to 7% in the final product in food contact applications in the MERCOSUR region.

Luminy® PDLA 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 and RES No 28/24.

Luminy® PDLA 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 amended by GMC RES 22/24.

Luminy® PDLA 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.

Based on testing that TotalEnergies Corbion has performed, Luminy® PDLA is suitable for use up to 7% in food contact application 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® PDLA 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