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Subject: Food contact compliance statements
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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 Total Corbion PLA (Thailand) Ltd:

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

The statements do not cover users:

- 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 abovementioned products [hereinafter called Luminy PLA] as supplied by Total Corbion PLA, 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, 71183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37 and 2019/988, 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 Total 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 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 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's Total Corbion PLA'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 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 Total Corbion PLA 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. Luminy PLA is not intended to be used in medical devices.

Luminy PLA neat resin is approved for all food types 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's Total Corbion PLA'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 Total Corbion PLA, 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 4806.6-2016 regarding National Food Safety Standard Food Contact Plastic Resin. 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. Total Corbion PLA strives to minimize the 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 4806.7-2016 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 Total Corbion PLA 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's Total Corbion PLA'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.

MERCOSUR

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 MERCOSUR region.

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. 2/12.

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. 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.

Based on testing that Total Corbion PLA has performed, Luminy PLA is suitable for use with all food types and is meeting the OML requirements of 50 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@total-corbion.com.



Floris Buijzen
Senior Product Market Manager