Regulatory Information Sheet

colorFabb PLA/PHA

Date of issue: May 16, 2017
Version: v1.0

colorFabb PLA/PHA printing filament is produced from a material compound, which is in compliance with the following legal requirements (in each case including all amendments in their currently valid versions):

European Union Food Contact (Regulation (EU) 10/2011 Annex IV)

- EU-Framework Regulation on materials and articles intended for food contact: (EC) No 1935/2004 of 27 October 2004
- German Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB) of 07 September 2005
- EU-Regulation on good manufacturing practice for materials and articles intended to come into contact with food: (EC) No. 2023/2006 of 22 December 2006

Specification of the intended use or limitations
Type or types of food with which it is intended to be put in contact: dry, aqueous, acidic and fatty foodstuffs

Time and temperature of treatment and storage in contact with the food: any condition of time at room temperature and below

Ratio of food contact surface area to volume used to establish the compliance of the material or article: 6 dm^2/kg food (maximum thickness 500 µm)

This compound is composed of substances listed in Annex I of Regulation EU No 10/2011 of 14. January 2011 only. For these substances no limitations and/or specifications have been stipulated in Regulation EU No 10/2011.

So called 'Dual Use Additives' are no part of this compound's recipe.

US Food and Drug Administration (FDA)
The raw materials of this compound meet the requirements of the US FDA for materials in contact with food: the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), provided the use is in accordance with good manufacturing practices.

For both aforementioned regulations the duty of care regarding the compliance of the compound within the legislation governing food contact applications has been fulfilled. It is the responsibility of every downstream user to verify the suitability of the compound for his own intended application. Liability for losses arising from inadequate use of the compound or any missing compliance is excluded.

Cosmetics Packaging
(Regulation (EU) 1223/2009 of November 30th 2009)
We confirm this compound is manufactured in accordance with this EU Regulation.

colorFabb B.V.
Bremweg 7
5951 DK Belfeld
The Netherlands

T +31 (0)77 – 4664015
F +31 (0)77 – 3971414
E sales@colorfabb.com
I colorfabb.com

KvK nr: 53498607
VAT nr: NL850902770B01
IBAN: NL54RABO0151849188
BIC: RABONL2U

Regulatory Information Sheet

colorFabb PLA/PHA

Date of issue: May 16, 2017
Version: v1.0

Packaging waste
(Directive 94/62/EC of 20 December 1994)
The heavy metals cadmium, lead, mercury and chromiumVI are not intentionally used in the manufacture of this compound. The sum of the heavy metals cadmium, lead, mercury and chromiumVI incidentally present in this compound is below 100 ppm. Therefore the compound complies with the limits set out in Directive 94/62/EC.

RoHS
(Directive 2011/65/EU of 8 June 2011)
We hereby confirm that this compound is manufactured without the intentional use of the following chemical substances:

- Lead
- Mercury
- Cadmium
- Hexavalent chromium
- Polybrominated diphenyl ethers (PBDE).

PFOS
(Directive 2006/122/EC of 12 December 2006)
We confirm this compound is manufactured without the intentional use of perfluorooctane sulfonates.

Safety of Toys (EN 71-3)
This compound complies with the requirements of European standard EN 71 regarding the safety of toys part 3: “migration of certain elements”. Please note this standard refers to finished toys only.

VOC
(Swiss ordinance on Volatile Organic Compounds (VOC) of 12 November 1997)
This compound is in compliance with the Swiss Ordinance on volatile organic compounds (VOC).

TSCA
(US Toxic Substances Control Act)
We confirm the listing of all raw materials of this compound within the TSCA inventory.

Allergens
This compound is manufactured without the intentional use of substances currently known to be or suspected of being food allergens. Furthermore it is manufactured without the use of ingredients listed in Annex IIIa of Directive 2007/86/EC and Annex III LMKV.

Active and intelligent materials (Regulation (EC) No. 450/2009)
This compound is manufactured without the use of active and intelligent materials.

Recycling (Regulation (EC) No. 282/2008)
This compound is manufactured without any recycled plastic materials.

BSE infection
This compound is manufactured without any derivatives of animal origin. There is no scientific reason to assume any risk of BSE transfer through this compound.

colorFabb B.V.
Bremweg 7
5951 DK Belfeld
The Netherlands

T +31 (0)77 – 4664015
F +31 (0)77 – 3971414
E sales@colorfabb.com
I colorfabb.com

KvK nr: 53498607
VAT nr: NL850902770B01
IBAN: NL54RABO0151849188
BIC: RABONL2U

Other absent substances
Furthermore we confirm that this compound is manufactured without the use of the following substances:

- Primary aromatic amines
- Polycyclic aromatic hydrocarbons (PAH)
- Phenols & Phenyphenole
- Bisphenol A and its derivatives
- Bisphenol F and its derivatives
- Bisphenol S and its derivatives
- Phthalates
- Adipates
- Maleicacid-di-(2-ethylhexyl)-ester
- Formaldehyde
- 2,2'-Dimethoxy-2-phenylacetophenone
- 2,4-Pentadione (synonyme acetylacetone)
- Acrylamide
- Adsorbable organically combined halogens (AOX)
- Azo dyes
- Benzophenone and 4-methylbenzophenone and their derivatives
- Brominated fire retardants
- Cobalt(II)-chloride (CAS 7646-79-9 (anhydrous))
- Cyanuric acid (1,3,5-triazin-2,4,6-triol)
- Dimethylfumarate (DMF)
- Elastomers or rubber from which n-nitrosamines may be released
- Epoxidised soybean oil (ESBO)
- 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE)
- Bis(-hydroxyphenyl)methane-bis-(2,3-epoxypropyl)ether (BFDGE)
- Novolac glycidyl ethers (NOGE)
- Ethyl-4-dimethylaminobenzoate
- Halogens
- Isopropylthioxanthone (ITX)
- Latex
- Melamine
- Chain- and ring-shaped hydrocarbons (MOSH, "mineral oil saturated hydrocarbons")
- Aromatic hydrocarbons (MOAH, "mineral oil aromatic hydrocarbons")
- Nanoparticles and -materials (< 100 nm)
- Diphenyl-2-ethylhexylphosphate (DPO)
- Tributyltin oxide (TBTO)
- Tributyltin (TBT)
- Perfluorinated organic compounds & Fluorinated surfactants
- Perfluorooctanoic acid (PFOA)
- Polycyclic aromatic hydrocarbons (PAHs)
- Semicarbazide (SEM)
- Titan-acetylacetonate (TAA)
- Triclosan
- Vinylchloride

colorFabb B.V.
Bremweg 7
5951 DK Belfeld
The Netherlands

T +31 (0)77 – 4664015
F +31 (0)77 – 3971414
E sales@colorfabb.com
I colorfabb.com

KvK nr: 53498607
VAT nr: NL850902770B01
IBAN: NL54RABO0151849188
BIC: RABONL2U

Regulatory Information Sheet

colorFabb PLA/PHA

Date of issue: May 16, 2017
Version: v1.0

Liability Limitation
Please note that this compound has not been tested for trace amounts of the substances aforementioned or listed within the regulations. However, based on the information obtained from upstream suppliers there is no reason to expect any of the substances listed to be present within this compound.

The values listed have been established on standardized test specimens at standard temperature and humidity conditions. The figures should be considered as guide values only. Under certain conditions the processing conditions can have a significant influence on the properties .

Customers must undertake their own determination of this product's suitability and completeness for their own use, for the protection of the environment, for the health and safety of their employees and purchasers of their products. No warranty is made of the merchantability or fitness of any product, and nothing herein waives any of the seller's conditions of sale.

The content of this document is strictly confidential and should not be passed on to third parties. However in case your customer requires this information in order to assess compliance as required by law, you are entitled to pass them on to the customer or a neutral institute given the information is treated strictly confidential also by them.

If further information is required please do not hesitate to contact us.

colorFabb B.V.
Bremweg 7
5951 DK Belfeld
The Netherlands

T +31 (0)77 – 4664015
F +31 (0)77 – 3971414
E sales@colorfabb.com
I colorfabb.com

KvK nr: 53498607
VAT nr: NL850902770B01
IBAN: NL54RABO0151849188
BIC: RABONL2U