

(b) (4)

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E-mail: (b) (6)

Lomma 23 October 2017

## Declaration of Compliance

Product number:

(b) (4)

Name:

## Introduction

The product is a concentrate and is not intended to come in direct contact with food. It should be diluted with other polymers and processed before the finish product will be in contact with food.

Cause of this circumstances (b) (4) can not give compliance for the finish product, it is the responsibility for the end producer to make relevant migrations tests.

This product information is based on the present state of our knowledge, information and experience. No responsibility or liability can be assumed for factors lying outside our knowledge and control.

## Framework Regulation 1935/2004/EC

All materials intended to come into contact with food are governed by the European Regulation (EC) No 1935/2004. According to Art.3 of the Framework regulation no food contact materials shall “transfer constituents into food at levels that endanger human health” and is supported by Regulation 2023/2006 on Good Manufacturing Practice.

Polymers and additives are regulated by Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No 2015/174, 2016/1416, 2017/752.

Colorants comply with the requirements in Resolution AP (89)1 “On the use of colorants in plastic materials coming into contact with food”. The resolution regulates migration, purity and heavy metals for pigments.

## Commission Regulation 10/2011/EC and its amendments

The polymers and intentionally added additives comply with the requirements of Regulation (EU) No. 10/2011 and its amendments Regulation.321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416 and 2017/752

It is up to the end producer of the product to make an assessment of overall migration and other release restrictions found in Annex I &II.

Information about SML and Dual Use will be finding under Restrictions and limitations.

## **Restrictions and limitations**

### **Polymers with SML**

Polymers with a Specific Migration Limit (SML):

No polymers with a Specific Migration Limit

### **Additives with SML:**

The following substances are restricted by SML values:

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### **Dual Use Additives:**

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### **Regulation 1907/2006/EC SVHC Substance of very high concern**

We declare that the product not contains over (b) (4) (w/w) of the Substances of Very High Concern (SVHC) according to ECHA's SVHC List of 16.12.2013 EU regulation 1907/2006.

### **European Resolution AP (89) 1**

Colorants comply with the requirements in Resolution AP (89)1 “On the use of colorants in plastic materials coming into contact with food”. The resolution regulates migration, purity and heavy metals for pigments.

### **Regulation EC 2023/2006/EC GMP and ISO 9001-2008**

**Good manufacturing practices for materials and articles intended to come into contact with food.**

We are ISO 9001-2008 certificated and we are following the requirements in regulation EC 2023/2006

## **Food contact statement USA (FDA)**

The requirements of the CFR Title 21 permit the use of the ingredients selected for use in

This masterbatch for incorporation into Plastics articles intended to come into contact with foodstuffs.

The components are specifically approved under CFR Title 21 as follows:

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21 CFR 178.3297

21 CFR 177.1520

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