

## **Regulatory Compliance Statement**

14.05.2020

**GAG BX-CG6GE04-1160000-100\_0-ZZZ**  
**SmartCycle® GAG BX-CG6GE74-7169450-100\_0-ZZZ**  
**GAG BX-CG6GE44-1160000-100\_0-ZZZ**  
**APET BX-E600F04-1160000-100\_0-ZZZ**  
**SmartCycle® APET BX-E660F04-1160000-100\_0-ZZZ**  
**PVC BX-M185/08-51/9500-100\_0-ZZZ**  
**VC PR-M180/09-04/8400-482D8-ZZZ**  
**VC PR-M280/90-51/8800-696\_2-ZZZ**

We confirm that our films comply with the following Regulations:

### **Allergens - Regulation (EU) No 1169/2011**

The products do not contain allergenic substances listed in Annex II of Regulation (EU) No 1169/2011. Films based on rigid PVC may contain epoxidized soya bean oil, which is chemically reacted from refined soy bean oil and therefore exempted as allergen according Annex II of Regulation (EU) No 1169/2011.

### **Azocolourants**

The products do not contain dangerous azocolourants according Directive 2002/61/EC amending Council Directive 76/769/EEC.

### **BPA (Bisphenol A)**

The products do not intentionally contain BPA (bisphenol A).

### **Bisphenols (others)**

The products do not intentionally contain other bisphenols like Bisphenol AF, Bisphenol AP, Bisphenol B, Bisphenol BP, Bisphenol C, Bisphenol E, Bisphenol F, Bisphenol FL, Bisphenol G, Bisphenol M, Bisphenol P, Bisphenol PH, Bisphenol S, Bisphenol TMC, Bisphenol Z.

### **Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE)**

The products may contain lubricants, which can be derived from animal tallow and are produced according to EMA/410/01 rev. 3 (2001/C 73/01) "note for guidance on minimising the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products" from 5<sup>th</sup> March 2011. The production of these tallow derivatives (fatty acid esters), according to this note for guidance, is regarded as safe concerning the risk of bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE).

### **Conflict Minerals**

The products do not contain and are not derived from so called "Conflict Minerals" as defined in the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Conflict Minerals are by definition cassiterite (tin), wolframite (tungsten), coltan (tantalum) and gold from the Democratic Republic of Kongo (DRC).

### **Dioxine**

The products do not contain dioxine and therefore Regulation (EU) No 252/2012 (related with dioxine and dioxine related PCB's in the food chain) is not applicable.

### **Epoxy Derivatives (BADGE, BFDGE; NOGE)**

The products do not contain epoxy derivates BADGE (2,2-Bis(4-hydroxyphenyl)propan-bis-(2,3-epoxypropyl)ether), BFDGE (Bis(-hydroxyphenyl)methan-bis-(2,3-epoxypropyl)ether), NOGE (Novolac-Glycidylether) in compliance with Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

### **Genetically-Modified Organisms (GMO)**

The products do not contain any genetically modified organisms (GMO).

### **Gluten**

The products do not contain gluten.

### **Halogenated flame retardants**

The products do not contain halogenated flame retardants.

### **Heavy Metals**

The products meet the requirements for heavy metal limits (mercury, cadmium, lead, hexavalent chromium) of 100 ppm according Directive 94/62/EC, as amended and the Toxic Packaging Clearing House (TPCH, formerly CONEG).

### **Latex**

The products do not contain natural latex and its derivatives.

### **Melamine**

The products do not contain melamine.

### **Mineral oil hydrocarbons residues – MOSH, MOAH**

The products do not contain mineral oil hydrocarbons like MOSH (mineral oil saturated hydrocarbons), MOAH (mineral oil aromatic hydrocarbons). Mineral oil hydrocarbons residues could be a concern of paperboards, which is not used in our plastic films. Paperboard can contain residues of mineral oil hydrocarbons from printing colors of newspapers when recycled paper is contained.

### **Nano-particles**

Nano-particles characterize a group from few to some thousand atoms or molecules. The name refers to its size, which is typically 1 to 100 nanometers. The products do not contain nano-particle coatings. Used additives such as titanium dioxide, silicates, colour pigments or fillers can contain particles as in the

above mentioned range. These are however stationary bound in the plastic matrix and therefore harmless.

#### **Ozone-Depleting Substances (ODS)**

The products do not contain any ozone-depleting substances, including those listed in Regulation (EC) No 1005/2009.

#### **PentaBDE, OctaBDE**

The products do not contain pentabromodiphenyl ether (pentaBDE) and octabromo-diphenyl ether (octaBDE) according Directive 2003/11/EC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether).

#### **Phthalates**

The products comply with Regulation (EU) 2018/2005 amending Annex XVII to Regulation (EC) No 1907/2006 relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles).

No phthalates, including di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), diisobutyl phthalate (DIBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP), are intentionally added to this product.

#### **Plasticizers**

The products do not contain plasticizers.

#### **Polycyclic aromatic hydrocarbons**

The products do not contain polycyclic aromatic hydrocarbons (PAHs).

#### **Primary aromatic amines (PAA)**

The products do not contain primary aromatic amines (PAA) above the limit of detection of 0,01 mg/kg.

#### **RoHS (Directive 2011/65/EU)**

The products comply with Directive 2011/65/EU – amendment of Directive 2002/95/EC and amended by Directive (EU) 2015/863. Lead, mercury, cadmium, hexavalent chromium, polybrominated Biphenyls (PBB), polybrominated Diphenylethers (PBDE), Deca-BDE, DEHP, BBP, DBP or DIBP are not used for the production of the above mentioned products.

#### **Vinyl chloride monomer (VCM)**

Films based on rigid PVC contain residual traces of vinyl chloride monomer in full compliance with the restriction according Regulation (EU) No 10/2011, 1 mg/kg in final product.

Yours sincerely,

Director Quality, Pharma,  
Health & Specialties

Regulatory Affairs Expert