müller+krempel
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Berry | Bramlage

BERRY BRAMLAGE BELLIGNAT

5 rue Castellion prolongée

01100 Bellignat

France

Date : September, 13th, 2019

DECLARATION

Concerned products:

6501XXXXXXXX BOTTLES AIRFREE VEGA 50 to 500ML BG P35 WHITE

Composition information

We certify that the composition of the product above mentioned is the following:

Bottle layer	In direct contact with the cosmetic product	Raw material	type	Eu. Pharmacopeia Compliance
External layer 1	NO	PP	homopolymer	NO
		White Masterbatch	inorganic	NO
External layer 2	No	PP + White Masterbatch	homopolymer	NO
			inorganic	NO
		PP + White Masterbatch+ slip agent *	organic	NO
			organic	NO
Poach external layer	NO	EvOH or Mix EvOH/PA *	Barrier layer r	No but complies with USP chapter 661 -Class VI for EvOH
Poach median layer	NO	Adhesiv	organic	NO
		PEHD	homopolymer	NO
Poach internal layer	YES	PEHD	homopolymer	NO

*: not described in EU. Ph. but the supplier can provide the full compositional formula under NDA and the material is submitted to pharmaceutical change control procedure.

Food contact compliance:

The materials used in the manufacturing of the products concerned by this declaration, are in conformity with the following norms:

- Regulation (EC) No 2023/2006 of the European Parliament and of the Council of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, and amendments.
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and amendments.
- Commission Regulation No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendments.
- USA Food contact FDA regulation. Polymers comply with 21 CFR 21 CFR 177/178, following chapter according the raw material concerned, chapters 21 CFR 177.1520 (Olefin polymers); 21 CFR 177.1395 (multilayers, laminates structures); 21 CFR 177.1390 (Laminate structures for use at temperatures of 250 deg. F and above), 177.1360 (Ethylene-vinyl acetate-vinyl alcohol copolymers); 175.105 (Adhesives), 178.3297 (Colorants for polymers).
  .1360 (Ethylene-vinyl acetate-vinyl alcohol copolymers); 175.105 (Adhesives), 178.3297 (Colorants for polymers).

However, we call back that no migration test are made by Berry Bramlage / Promens S.A. on the concerned products, so Promens S.A. can guaranty the conformity of the materials only.

If the products concerned by this declaration are intended to come into contact with food, it pertains to the purchaser to perform migration tests, following the specific end-use conditions of use as described in Regulation (EU) 10/2011 (Annex III and Annex V), and to ensure that the material does not bring about an unacceptable change in the composition of the food, or bring about deterioration in the organoleptic characteristics which render it unfit.

Siège social / Registered office : Promens SA

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*Substances presence or use information**

We can confirm that the substances listed below are not intentionally added or use nether in the raw materials used, nor during the manufacturing process of the concerned product:

- Bisphenol A, F, and derivate
- Melamine
- Gluten and other food allergens
- Latex
- Phthalates: traces of phthalates may be found in the polypropylene external layers as catalysis system residues but at rate < 1 ppm.
- Parabens
- Carcinogenic, Mutagenic, toxic for Reproduction substances (CMR) as defined in the CLP regulation 1272/2008
- Known Endocrine disruptors: Phthalates, Bisphenols, Paraben (see the concerned points).
  We haven't got any data on others potentially endocrine disruptor substances category I & II mentioned in annex 13 of the final report of BKH study 2000.
- MOAH, MOSH: trace amount of mineral oil can be present in parts of polypropylene as a manufacturing process residue. This Mineral Oil is included in the Union List of the authorized substances for the manufacturing of plastic materials intended to come into contact with food (Regulation 10/2011/EC).
- Substances described in the annexes II of Cosmetic Regulation, (EC) N° 1223/2009 of the European Parliament and of the Council 30 November 2009 on cosmetic products, as amended.
- Genetically modified organisms: the product complies with directive2001/18/EC.
- Nanomaterials (as defined in Cosmetic regulation 1223/2009 or in EU Commission Recommendation of 18 October 2011 (2011/696/EU) including rutile titan dioxide: the TiO2 contained in the colorant is in a polymer matrix.
- Material blood or blood derivatives.

With the exception of EvOH layer (layer 3), for which declarations of the supplier specify absence of intentionally added substances, we don't have specific information from our raw material suppliers for the following substances:

- Substances described in the annexes III of Cosmetic Regulation, (EC) N° 1223/2009 of the European Parliament and of the Council 30 November 2009 on cosmetic products, as amended.
- Skin sensitizers under CLP legislation 1272/2008 Category 1A, 1B or 2.

But these substances, at our best of knowledge, on the basis of the substance guideline of the task force cosmetic Europe on substances used as Food contact materials, are not used as additive in the plastic raw materials used for the fabrication of the parts, and are not intentionally added by Berry Bramlage/Promens SA.

Berry Bramlage - Promens S.A. manufactures all the concerned products using Good Manufacturing Practice so we have no reason to expect the presence of all substances above described, but no analytical tests are made on the concerned products, so we cannot guarantee that there is no trace amount of these substances, as impurity or otherwise.

*Animal Origin substances - BSE (Bovine Spongiform Encephalopathy) /TSE (Transmisible Spongiform Encephalopathy) risk**

Animal origin substances are not used in the raw material used for the fabrication of the product and No animal origin substances are directly used by Berry Bramlage / Promens SA neither during the fabrication of the product nor in the plant where the product is fabricated, that avoid any cross-contamination risk for BSE/TSE.

Based on our knowledge of the raw materials (raw materials certificates) and of the processes used in the manufacturing of the product concerned by this declaration, knowing that the process used for the fabrication involves high temperatures (dry heat with temperature

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> 200°C) and high pressures (between 300 and 1200 bar), we have no reason to expect that these products could present a risk for TSE or viral contamination[1] even if guidance EMA/410/01 Rev.3, that concerns medical devices, is not directly applied .

Directive 94/62/EC - packaging waste directive:

We certify that the regulated metals – lead, mercury, cadmium, and hexavalent chromium - are not intentionally added in the concerned product during the manufacturing process.
The packaging above mentioned comply with the Directive 94/62/EC as well as the heavy metals level, that is the total concentration levels of lead, cadmium, mercury and hexavalent chromium shall not exceed 100 ppm by weight in the packaging.

However, we call back that no analytical tests are made by Berry Bramlage / Promens S.A. on the concerned products, so we cannot guarantee that there is no trace amount of these substances, as impurity or otherwise.

Reach Regulation (1907/2006/EC)

At Berry Bramlage / Promens S.A. we do not add substances or use manufacturing processes in our business that requires us to pre-register or register any of our products under the REACH legislation. The registration requirement is imposed on our suppliers.

Our role is to make sure that the chemical substances we use to manufacture our products are dealt with in accordance with the legislation. Berry Bramlage / Promens S.A. is therefore implementing procedures to accommodate the REACH rules. As part of our procedure we have approached all our suppliers, enquiring about their REACH preparations and compliance hereto.

The products concerned by this declaration do not contain any substances of very high concern (SVHC) which are included in the "candidate list" , exceeding more than 0.1%(weight/weight) in the packaging, taking into account in particular the evolutions of the 'candidate list.
http://echa.europa.eu/chem_data/candidate_list_table_en.asp

Californian proposition 65 listed substances presence information:

Traces of phthalates may be found in Polypropylene parts at a rate < 1ppm: see special paragraph above
We declare the presence of Titanium dioxide in the part colored in white, but molecules are not free in a powder shape but are encapsulated in a polymeric matrix. So, they present no risk according Californian Proposition 65.
So we have no reason to suspect that the packaging could not comply with Californian Proposition 65 requirements.

If a new substance were to enter into the composition of these products beyond the prescribed rate, we will inform you.

The present certificate is valid for five years. Upon the expiration of this certificate, we can issue a new one at your request.

Christine Borge
Research Engineer

[1]: Barbeau J. , El Moualij B., Heinen E., Zorzy W. 2006, Transmission et résistance des prions : la pratique de la médecine dentaire en sera-t-elle affectée ?, *Journal de l'ordre des dentistes du Québec*, Volume 43 : 461-467

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