

Date : February, 20<sup>th</sup>, 2020

## DECLARATION

### Concerned products:

**4160401XXXXX - PUMPS ECOSOLUTION MV Standard**  
SHORT Or LONG Actuator / White or Natural / Without or Without cap

### Composition information

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

Component	référence	In direct contact with	référence	Raw material	type	E. Pharmacopeia
Actuators V2 (short or long version)		yes		PP	homopolymer	NO
				White Masterbatch	inorganic	NO
BELLOW P4P HV bi-injected	injection 1	yes	injection 1	ULDPE 1	elastomer	NO
				Slip agent		NO
P4P BASE PP		yes		PP	homopolymer	NO
				white Masterbatch	inorganic	NO
P4P PLUG MV BIMATERIAL NAT CHARGE TALC	material 1	No	material 1	PP	homopolymer	NO
				ULDPE	elastomer	NO
	material 2 (overmolded)	yes	material 2 (overmolded)	Talc	mineral	NO
				Slip agent	organic	NO
				ULDPE	elastomer	NO
P4P OVERCAP narural		no		PP	Copolymer stat	NO

### Food contact compliance:

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

- o 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.
- o 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.
- o Commission Regulation No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendments
- o USA Food contact: FDA – Polymers comply with 21 CFR, chapters 21 CFR 177.1520 (Olefin polymers); 21 CFR 178.3297 (Colorants for polymers).

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.

#### Substances presence or use information

We can confirm that the substances listed below **are not intentionally added or use** neither in the raw materials used, nor during the manufacturing process of the concerned product:

- Recycled plastic materials
- Bisphenol A, F, S and derivate
- Melamine
- Gluten and other food allergens
- Latex
- Phthalates: traces of phthalates may be found in parts in polypropylene parts, such as the actuator, as catalysis system residues but at rate < 1 ppm.
- Carcinogenic, Mutagenic, toxic for Reproduction substances (CMR) as defined in the CLP regulation 1272/2008: except for traces of a not intentionally added CMR cat 2 substance, with criteria set out in section 3.5, 3.6 & 3.7 of the annex I of regulation 1272/2008/EC, that may be found in ULDPE parts. Information on the nature and on precise rate is not given by the raw material supplier.
- Endocrine disruptors: For Phthalates, and Bisphenols, please see the concerned points above.  
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.
- 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
- 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 white colorants is in a polymer matrix.
- Material blood or blood derivatives.

We don't have specific information from all our raw material suppliers for the following substances:

- Skin sensitizers under CLP legislation 1272/2008 Category 1, 1A or1B
- Parabens.

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

We have specific declaration from our supplier that specify that **Animal origin substances are not used** in the raw material,  
**Except for:**

- The ULDPE raw materials used for the below and for the plug fabrication
- The PP used for the fabrication of the base and of the actuator

that contain animal origin substances, like stearates or tallow derivatives substances, which are in conformity with the guidance EMA/410/01 Rev.3 of July 1, 2011 except for the slipping agent added in the plug and in the bellow.

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 > 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<sup>1</sup> 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)

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](http://echa.europa.eu/chem_data/candidate_list_table_en.asp)

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

---

<sup>1</sup>: 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

SVHC presence information:

Traces of phthalates may be found in Polypropylene parts at a rate < 1ppm: see special paragraph above.

Californian proposition 65 listed substances presence information:

Traces of phthalates may be found in Polypropylene parts at a rate < 1ppm: see special paragraph above  
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.

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

