# Item: ABB15A3B002-200

## Mist sprayer Classic 24/410, PP, black, ribbed, dose 0.14ml, black overcap (Virgo/Draco 200)

Old code: SPV-D0.14-G24-KSW-SW

For the above mentioned product, the following is hereby confirmed:

The Cosmetic Regulation (EC) 1223/2009 refers principally to the cosmetic formulation and not to the packaging thereof. Nevertheless, the provision of some information concerning the packaging material is required – Annex I, Part A, 4, information about packaging material – the relevant characteristics of packaging material, in particular purity and stability.

The Regulation is not specific regarding the requirement of cosmetic packaging. Due to this lack of clarity, it is commonly accepted that the legislative requirements of packaging for food contact are useful references for cosmetic packaging. A recent guideline from the EU Commission states that "*reference to Regulation (EC) No 1935/2004 on food contact materials could be useful for characteristics of packaging materials".* However, the producer applies the food contact legislation as far as it is relevant for cosmetic packaging.

***REACH Regulation***

The producer certifies that the packaging is strictly in accordance with the REACH Regulation EC no. 1907/2006 and in particular complies with the restrictions included in annex XVII and with the authorizations/bans included in annex XIV and commits to inform of any compliance gap in relation to REACH Regulation.

As a producer of articles, the producer is well aware of their duty to communicate information related to Substances of Very High Concern (SVHC), in accordance with Article 33 of the REACH Regulation. The producer confirms that they monitor the REACH candidate list, and that they are aware of the latest additions to the list of SVHCs, published on the ECHA website January 17th, 2023.

The suppliers of raw materials and components also have a duty to inform if their products contain substances on the SVHC candidate list at a concentration above 0.1% w/w. In the event of notification by the raw materials suppliers of the existence of one of the substances exceeding the 0.1% w/w threshold, the producer will inform as soon as possible.

The producer also confirms that:

- They do not add any of these substances during the manufacturing process.
- They do not manufacture articles which contain substances intended to be released under normal or reasonably foreseeable conditions of use.

***Packaging and packaging wase Regulation***

The producer certifies that the packaging complies with the Directive 94/62/EC as well as with CONEG (Coalition of Northeastern Governors) legislation with regards to heavy metals level: the total concentration levels of lead, Cadmium, mercury and hexavalent chromium shall not exceed 100 ppm by weight in the packaging.

***Food contact Europe***

Regulation EU 1935/2004 on materials and articles intended to come into contact with food.
Plastics - EU Regulation 10/2011 Plastics intended to come into contact with foodstuffs
Silicones - Council of Europe Resolution AP (2004)5 Silicones used for food contact applications
*Compliance with the stated regulations is limited to the chemical composition.*

***Food contact US***

Stated chapters of FDA 21CFR or FCN (Food Contact substance Notification)
*Compliance with the stated regulation is limited to the chemical composition.*

The producer has no access to the detailed composition of raw materials, and does not, routinely, carry out any chemical analysis of these materials. The presence of non-intentionally added substances cannot therefore be totally excluded, and as a consequence, provision of "Free of" certificates is not possible. The producer does not implement migration studies on the finished products as it has no control over neither the nature nor composition of the product with which it is filled.

This document does not exempt the customer from ensuring the compatibility of the packaging requested with his product and verifying that the finished product conforms to the analytical requirements (specific and/or global migration, restriction and/or specification) according to the expected conditions of use of the product.

This statement is based on the current state of knowledge and related to above mentioned product.

***Nanomaterials***

Based on information from the supplier, it can be stated that the release of any significant quantities of nanomaterials present in cosmetic and food packaging composed of food grade materials is not anticipated under normal and reasonably foreseeable conditions of use.

The producer does not intentionally use nanomaterials in the manufacture of the above mentioned product. However, they do not test for the absence of these substances in the raw materials they use.

***Bisphenosl A and S***

Bisphenol A (BPA) and S (BPS) are authorized in food contact applications in Europe and in the US.
The European Regulation 10/2011 authorizes BPA and BPS as a monomer/starting substance in plastics for food contact, but sets migration limits and/or restrictions to these substances. Both BPA and BPS are subject to a Specific Migration Limit (SML) of 0.05 mg/kg.

The producer is well aware that the EU Regulation No 1223/2009 on cosmetic products prohibits the use of BPA in cosmetic formulation. However, the text is not specific regarding the packaging. Due to the lack of clarity, it is commonly admitted that the legislative requirements of packaging for food contact are useful references for cosmetic packaging.
The EU Commission Decision (N° 2013/674/EU) on Annex I to the cosmetics regulation states that reference to food contact legislation could be useful for characteristics of packaging materials.

Our producer commits to using food grade plastics as much as possible.
However, the use of such materials does not exclude the migration of trace amounts of BPA and BPS to the cosmetic product. The EU Regulation on cosmetics states, in article 17, that “the non-intended presence of a small quantity of a prohibited substance, stemming from […] migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is safe for human health”. According to EFSA, BPA poses no health risk to consumers because current exposure to the chemical is too low to cause harm.

To the best of the producers’ knowledge, BPA is only used in the manufacture of epoxy, PVC, thermal paper, polycarbonate resins, and other polymers (e.g. polysulfones, polyamides, etc.), while BPS is used as a monomer in synthetic polymers such as polyethersulfone (PES) and polysulfone (PSU), as well as in epoxy resins. The producer only uses polycarbonate for non-contact components.
Therefore, although the producer cannot guarantee the complete absence of BPA and BPS in its materials, their presence can reasonably be excluded unless the product contains one of the aforementioned resins.

***Phthalates Statement***

The producer aims to use only materials that meet the compositional requirements of food contact legislation. The use of such materials however does not exclude the presence of traces of phthalates in the packaging material. The producer does not intentionally use phthalates in the manufacture of its packaging articles. However, the producer does not test for the absence of these substances in the above mentioned product.

***BSE/TSE Statement***

Our producer confirms that the above mentioned product, even if manufactured from starting substances or additives which may be of animal origin, presents no BSE risk.

On the basis of current scientific knowledge, the presence of TSE either in plastic polymers or in the final plastic articles is unexpected.

***CMR***

The producer does not intentionally add any CMR substances during the manufacturing of the above mentioned product. However, they do not routinely test for the absence of CMRs in the packaging materials.

The above mentioned statements does not release the user from the responsibility to review that the above mentioned product is suitable for the intended application.

***PFAS statement***

The producer confirms that they do not have intentionally added PFAS in the above mentioned product. They are, however, in the process of surveying all of their suppliers as they may use PFAS in their production process.

***Storage and Transport***

There are no special requirements to temperature or humidity. However, high fluctuations in temperature have to be avoided, so that no condensation could be caused. Furthermore, a temperature above 45°C should be avoided, to prevent distortion.

- Screen off from direct thermal radiation (distance at least 1m) and protect from direct solar radiation.
- Storage in closed areas, protect against direct wetness and frost proof store
- Protect from mechanical effects, packaging should not be damaged.

## Product information

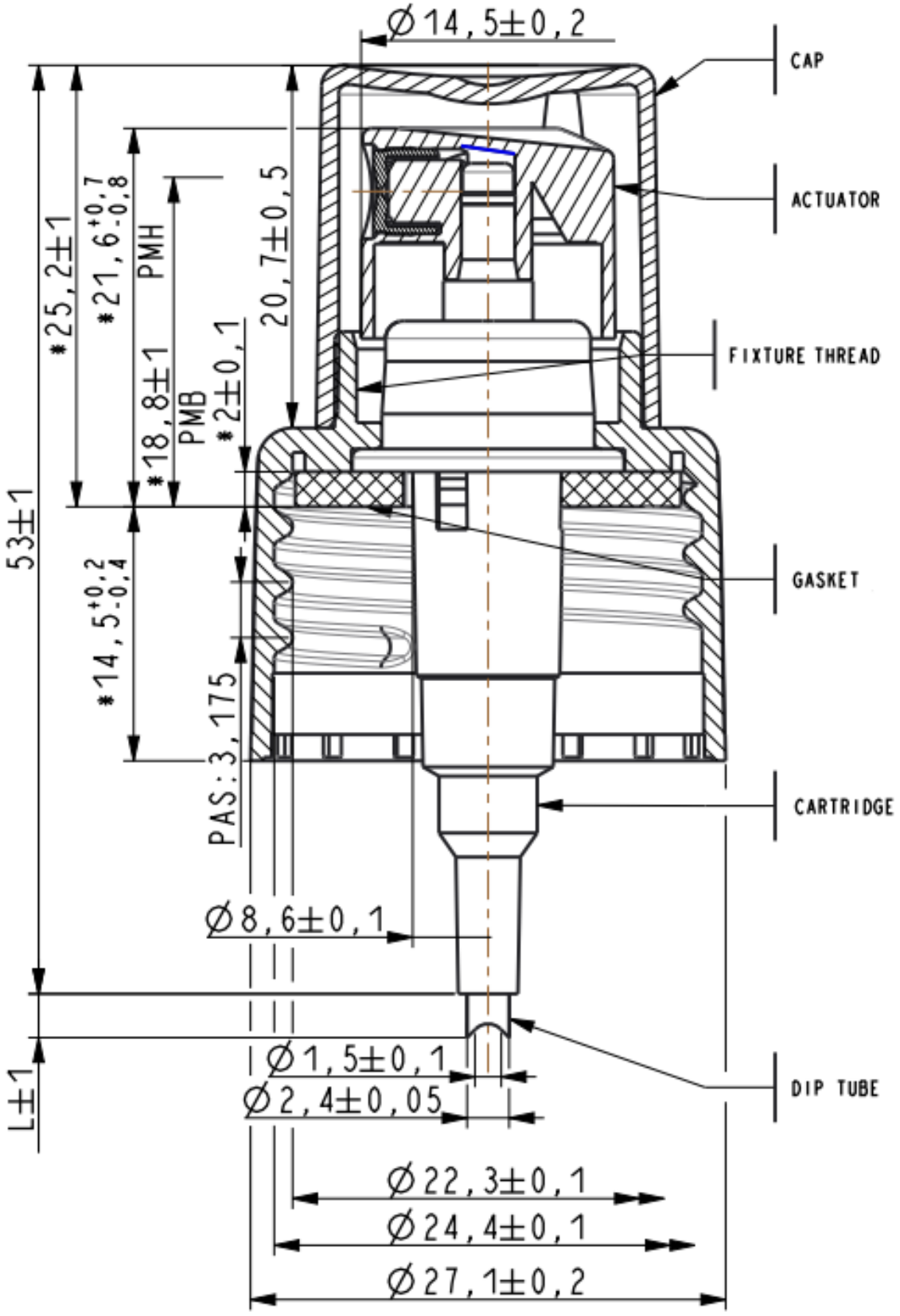
| MATERIAL | | REGULATORY INFORMATION | | | | INTERACTION BLUK/PACKAGING |
|---|---|---|---|---|---|---|
| COMPONENTS | NATURE | REACH: Article 33 | Food Contact: Europe | Food Contact: US | Heavy Metals: Eu Dir 94/62 | Contact Yes/No |
| CAP | PP R | ok | ok | 177.1520 | ok | No |
| FIXTURE THREAD | PP H | ok | ok | 177.1520 | ok | No |
| ACTUATOR | PP H | ok | ok | 177.1520 176.170 | ok | Yes |
| DIPTUBE | LDPE | ok | ok | 177.1520 | ok | Yes |
| | PP H | ok | ok | 177.1520 | ok | |
| GASKET | NBR | ok | ok | 177.2600 | ok | Yes |
| ADAPTER | POM C | ok | ok | 177.2470 | ok | Yes |
| PISTON | LDPE | ok | ok | 177.1520 176.170 | ok | Yes |
| | Silicone | ok | ok | 175.300 178.3570 | ok | |
| STEM | POM C | ok | ok | 177.2470 | ok | Yes |
| | Silicone | ok | ok | 175.300 178.3570 | ok | |
| HOUSING CAP | PP H | ok | ok | 177.1520 | ok | Yes |
| HOUSING | PP H | ok | ok | 177.1520 | ok | Yes |
| BALL | Stainless steel | N/A | N/A | N/A | ok | Yes |
| SPRING | Stainless steel | N/A | N/A | N/A | ok | Yes |

Dip tube length (FBOC): 116 mm

N/A: Non applicable
Ok: Compliance with the stated regulations is limited to the chemical composition

Components may be coloured and, as a general rule, the regulatory status of colorants is not reported in the table above. All colorants involved do not contain any SVHC > 0.1%, and comply with EU Dir. 94/62 (heavy metals content).

## Technical drawing (ABB15A3B002-200)

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