

Item: EGC00A1C001-200**Disc liner, PE, black (Ceres 100)**

Old code: ADS-CDS100

For our above mentioned product the following is hereby confirmed:

The colorants used for coloring polymers consist of mixtures of different pigments and carrier materials. The colorants correspond to the purity laws of the European Union Resolution AP (89) 1 (about the use of colorants in plastic materials in contact with food) and / or the BfR Recommendation IX. The colorants and plastics contain additives that are in accordance with Regulation (EC) 10/2011 including the amendments to Regulation (EC) 321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338, 2020/1245. The contained raw materials are compliant with the FDA regulation 21 CFR § 178.3297 Colorants for polymers and § 177.1520 olefin polymers. The FDA conformity for above color cannot be confirmed.

According to the manufacturer's specifications, the plastics (polyolefins) used comply with Regulation (EC) No. 10/2011 of January 14, 2011 and subsequent amendments with regard to composition and purity. The composition also meets the *requirements of FDA regulation 21 CFR 177.1520 "Olefin polymers" as well as the *requirements of the European Pharmacopoeia, 10th edition including current addendum, Chap. 3.1.3 "Polyolefins"; 3.1.4 "Polyethylene without additives for containers for parenteral and ophthalmic preparations"; 3.1.5 "Polyethylene with additives for containers for parenteral and ophthalmic preparations"; 3.1.6 "Polypropylene for containers and closures for parenteral and ophthalmic preparations" and chapter 3.2.2 "Plastic containers and closures for pharmaceutical use". (*if applicable) Polymer grade meets the requirements of USP Chapter 661 (United State Pharmacopeia 44 - NF 39).

California Proposition 65

None of the ingredients are expected to cause any contravention of the Regulation of Safe Drinking Water and Toxic Enforcement Act of 1986, or the California Proposition 65. Based on data provided by our suppliers of the ingredients used in the manufacture of this product. The producer informs the customer that the following substances are used listed on the Proposition list:

- n-Hexane, not in a for that the substance can be released to the environment
- Titanium dioxide, embedded in a polymer, not in the forms of airborne, unbound particles of Respirable size as mentioned in the Proposition list,

Since the presence of listed substances is not expected under normal and foreseeable circumstances, the producers does not actively check their absence.

The overall concentration level of heavy metals (lead, cadmium, mercury and hexavalent chromium) of each component corresponds to the directive 94/62/EG (including its amendments) and is less than 100 ppm.

REACH Statement

According to information from the suppliers and the documents available, the materials and raw materials used for the manufacture of the products comply with the obligations and requirements resulting from the REACH Regulation. This statement is based on the confirmations of the suppliers.

Phthalat Statement

The producer can not confirm that their product is generally phthalate-free. Partly it may happen that traces of certain phthalates are present in the raw materials due the production.

BSE/TSE Statement

Calcium stearate may be used as a processing aid in the production of the raw material. According to the supplier, this can be obtained synthetically but also from animal products (tallow). However, the supplier cannot trace the source of the calcium stearate. For this reason, individual components that are necessary for the production of the raw material may come from animal sources. If applicable, the producer can confirm with reference to the supplier documents that the regulations 1069/2009/EC, 142/2011/EC, and "Note for Guidance EMA/410/01" are complied with. Furthermore, the producer confirms that no additional materials or additives are used in their manufacturing process that are of animal origin or that come into contact with them.

BPA Statement

Our producer confirms that, according to the information provided by their material manufacturers, bisphenol A is not intentionally added during production or formulation. However, the materials used have not been tested for Bisphenol A. The producer also do not add any Bisphenol A when producing the above mentioned product.

PFAS

According to the information given by the supplier and the processing, manufacturing aids, etc. the producer confirms that the above mentioned product does not intentionally contain:

Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) as defined in 2021 by the OECD and includes any man-made material that has been produced via fluorination chemistry with the end product containing a carbon atom either disubstituted with fluorine (CF₂) or fully fluorinated (CF₃).

PCR Statement

Raw material do not contain any post-consumer recycling material.

The resistance of the material towards the filling medium and a possible transition of materials to the filling medium mainly depend on the filling medium itself. Therefore the bottling company is required to test the final product under practical conditions for resistance, colour fastness and dosing suitability of the packing material.

Global Food Contact Status:

This product complies with the relevant requirements of (Plastics) Regulation (EU) 10/2011/EC, last updates (EU) 2019/07 from 11 January 2019 amending Regulation (EU) 10/2011, (Framework) Regulation (EU) 1935/2004 and (GMP) Regulation (EU) 2023/2006."

ICH Harmonized Guideline Q3D (Elemental Impurities)

The elemental impurities of Class 1, 2, 3 listed in the ICH Harmonized Guideline Q3D of 22 March 2019 are not intentionally used in the manufacture or formulation of this product. However this product has not been tested for these substances.

Raw material

The materials utilized for manufacturing the abovementioned product material comply with the European and American regulations for materials in contact with foodstuffs and the corresponding stipulations for packing materials.

The customer himself has to test the resistance with the respective filling and under the specific operation conditions.

Instructions of technical application

Removable to reach the contents.

Storage and Transport

- It is recommended to store the product at room temperature between 15 and 30°C and a relative humidity between 30 and 75% (at least 24h before processing).
- The product must be protected from direct sunlight and high atmospheric humidity during storage. Large fluctuations in ambient temperature and high atmospheric humidity may lead to moisture condensing inside the packaging.

All information is based on the datasheets from the raw material suppliers. Our producer assumes no liability for this.

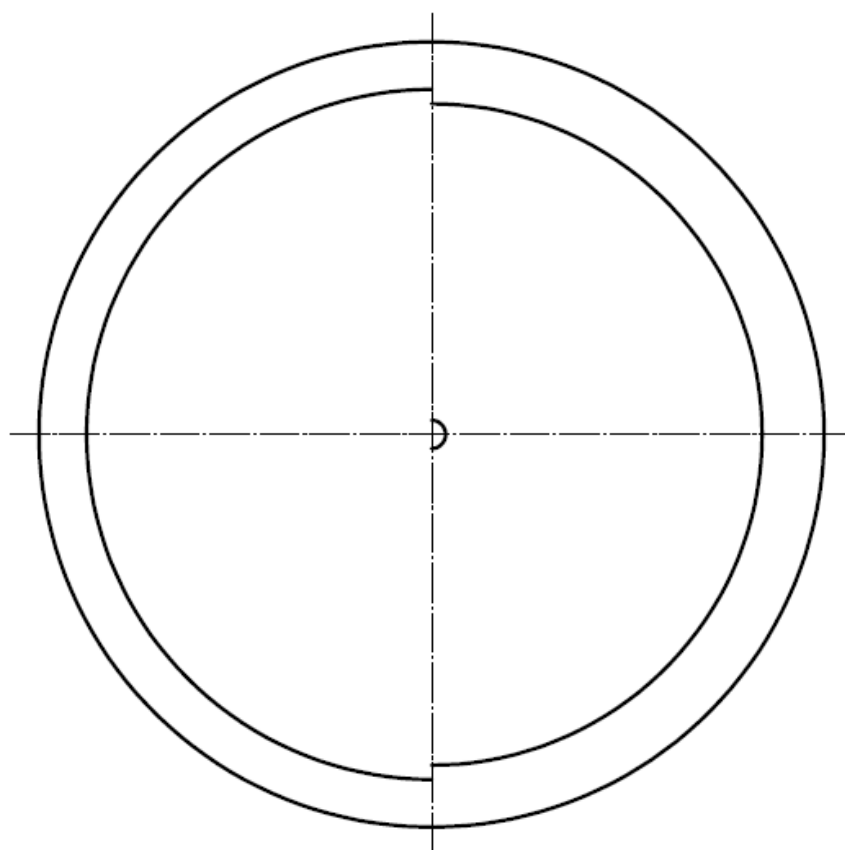
Product information

Cap

Material: PE Purell

Colouring: Black

Weight: 2,2g



Tolerance $\pm 0,2\text{mm}$



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