

6207-0xxx Sample tubes aseptic, with seal

Our supplier hereby confirms that all products mentioned above of composition containing:

Base Resin: Polypropylene (PP) EEC Ref# 81060 CAS 9003-07-0

This product contains one or more components with Specific Migration Limits (SMLs) 9,9-bis(methoxymethyl)-9H-fluorene Ref# 39815, SML = 0.05 mg/Kg

Expressed as Aluminium, SML = 1 mg/Kg

Dual Use Additives:

E211 Sodium Benzoate

E471 Mono- and diglycerides of fatty acids

European Union

- Is authorized by the regulation and corresponding specifications in force for the manufacturing of materials for use in contact with food in the EU member states that have specific requirements relating to such material beyond the EU Monomers Directive (Commission Directive 90/128/EEC) and the EU Monomers Directive (Commission Directive 2001/62/EC), as amended.

- Supports EU Packaging Directive 94/62/CE and amendments.

- Complies with Commission Regulation (EU) No 2023/2006.

- Satisfies the requirements of the EU Regulation on plastic materials and articles intended to come into contact with food (Council Regulation 10/2011 EC), EU Framework Directive on food contact materials (Parliament and Council Regulation 1935/2004/EC) and the Monomers Directive on food contact plastics (Commission Directive 2005/79/EC), as amended.

FDA

Satisfies the requirements of the applicable Food and Drug Administration (FDA) Food Additive Regulations, found in parts 177.1350, 177.1520, 182.1 and 182.2727 of the Code of Federal Regulations (CFR) for food use and complies with Title 21CFR 170.39. Our DMF no. 14789 has been filed with the FDA.

RoHS

The European Union's RoHS 3 Directive 2015/863 restricts the ten materials listed in the following table:

Material	Quantlty Limit Bv Mass
Lead (Pb) Hexavalent Chromium (Cr(VI)) Polybrominated Biphenyls (PBB) Polybrominated Diphenyl Ethers (PBDE) Bis(2-Ethylhexyl) phthalate (DEHP) Benzyl butyl phthalate (BPP) Dibutyl phthalate (DBP) Diisobutyl phthalate (DIBP)	0.1% (1000 PPM)
Cadmium (Cd) Mercury (Hg)	0.01% (100 PPM)

- We declare that the composition of the products listed below do not contain (intentionally added during their manufacture) any of the ten RoHS-restricted materials. The content of these restricted materials are non-detectable and therefore less than the applicable limits shown in the table above. The composition of the listed products below complies with the requirements for European Union (EU) Restriction of certain Hazardous Substances, as defined in Directive 2011/65/EU Annex II (RoHS); recasting 2002/95/EC.

Allergens

We state that the raw materials and processing aids used in the production of the above product here mentioned above have been reviewed and determined that it does not contain any known allergens as defined by European Directive 2003/89/EC of November 2003 and any subsequent amendments or the US FDA Food Allergen Labelling and Consumer Protection Act of 2004, Section 201 of the Federal Food Drug and Device Cosmetic Act. In addition, the equipment used for manufacturing these products is not used for the manufacture of other products that use or contain any allergens.

CONEG/EU Directive 94/62/EC/ Heavy Metals

We certify that regulated metals -lead, mercury, cadmium, and hexavalent chromium- were not intentionally added to any package or packaging component during the manufacturing process. Testing for heavy metals - cadmium, hexavalent chromium, lead and mercury- resulted in a total for all metals detected in any package or package component not exceeding 100 parts per million by weight.

BST/TSE

Tallow derived materials used in this product fulfil the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the Note for Guidance EMA/410/01, and as amended.

BPA

Bisphenol A, Melamine, Phthalates are not used as additives or functional components in this formulation. The fact that these substances are not used as functional components does not exclude that trace levels of these substances may be present as a result of the specific characteristics of the raw materials and/or manufacturing processes used for the above products.

Latex

This product mentioned above has been reviewed and to the best of our knowledge, the materials used, manufactured, and processed do not contain natural latex rubber or dry natural rubber.

Pesticides

Products manufactured at CSP Technologies are free of pesticides. The products manufactured at CSP Technologies, the raw materials used to manufacture them and the packaging materials are not exposed to pesticides or pesticide residue. We have strict pest control policies at our manufacturing facilities. Pest Control is contracted to a license pest management 3rd party company. Pesticides are not stored on site, nor used in the manufacturing or warehouse areas.

This product does not contain:

- Nanomaterials
- Phthalates
- GMO

ZERTIFIKAT CERTIFICATE

Pumpen | Probenehmer | Laborbedarf
für Labor, Industrie und Wissenschaft

Pumps | Sampling | Plastic Labware
for Laboratory, Industry, Science



The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier - Bürkle GmbH in Bad Bellingen/Germany - is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 2284-08

06. February 2019

A handwritten signature in blue ink, appearing to read "M. Saint-Denis".

Bürkle GmbH, Bad Bellingen,
Martin Saint-Denis, Managing Director

