



Effective Date: August 16, 2021

## REGULATORY INFORMATION PACKET

# Celcon<sup>®</sup> M90<sup>™</sup> Natural

ACETAL COPOLYMER

### **Product Manufacturer**

This product is manufactured by Celanese in Florence, KY and Bishop, TX, U.S.A.

### **Manufacturing Facility Certifications**

ISO 9001, FDA, UL, NSF and USP Class VI.

### **Chemical Inventories**

Please see SDS for chemical inventory listings.

### **Food Contact Status**

This product complies with the Food Contact Framework Regulation (EC) 1935/2004 and the guidelines laid down in the Regulation (EC) 2023/2006.

### **EU: Regulation (EU) 10/2011**

The monomers and additives used for the manufacturing of the above mentioned product are listed in the regulation (EU) 10/2011 from January 14th, 2011.

The above mentioned polymer compounds contain monomers and additives which are regulated with a specific migration limit. If required, confidential formulation information disclosed to a suitable third party test institute (laboratory) on the basis of a secrecy agreement.

Food regulations in Europe, finished plastic article needs to comply with, amongst other things, Overall Migration Limit requirements and Specific Migration Limits as specified in (EU) 10/2011 when tested on the food contact surface with the appropriate food simulants and time/temperature test conditions is the responsibility of the manufacturer of the final article.

**This product has been assessed under FDA Drug Master File No. 16661.**

### **USA: FDA CFR21**

This product is compliant with applicable FDA regulations for food contact. This product is formulated using polyacetal base resin that is compliant for use in food contact applications according to (CFR), Title 21, 177.2470. Any additives, that may be present, comply with appropriate, specific FDA Regulations.

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**Restrictions:**

Types of food	All food types except foods containing 15% or more alcohol.
Conditions of Use	A thorough H, as listed in Table 2 of 21 CFR 175.300(d); use temperature not to exceed 250 °F per 177.2470.
Application	Repeat Use Articles only.

**Food Allergens**

To the best of our knowledge, although this material does not fall under the scope of the FDA allergen guidelines; to help economic operators in the supply chain to comply with the rules laid down in the supplier’s guidelines, certifies that based on the manufacturing process and the raw materials used, are not made from and do not come into contact with these allergens: dairy products, eggs, peanuts, tree nuts, fish, crustaceans, soy, wheat fish, shellfish, celery, MSG, natural rubber/latex sulfites.

**US Pharmacopeia (USP)**

This product has not been assessed under US Pharmacopeia (USP).

**European Pharmacopoeia (EPHC)**

This product has not been assessed under European Pharmacopoeia.

**Animal Derived Components (BSE/TSE)**

This product does not contain any animal derived materials as intentional ingredients. Any of the wax additives used in this material can be considered compliant to EMEA-BSE regulation 2004/C24/03.

**Plant Derived Components**

This product is not known to contain additives/substances synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives.

**Kosher**

This material is not Kosher certified, the supplier does not use animal materials in a direct way to produce the additive; however, the production of the waxes may use raw materials that could be derived from animal origin. The formulation of this resin does not contain any animal derived materials as intentional ingredients.

**Halal**

This product is not Halal certified, the supplier does not use animal materials in a direct way to produce the additive; however, the production of the waxes may use raw materials that could be derived from animal origin. The formulation of this resin does not contain any animal derived materials as intentional ingredients.



## **REACH 219 Substances (July 8, 2021)**

European Union legislation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals, 1907/2006/EC): This product is in compliance with the EU regulation 1907/2006/EC. not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet that would require reporting under this regulation.

This polymer product is not directly subject to the registration requirements under REACH. Polymers are excluded from registration obligations under REACH. However, the constituents of these polymers and in particular the constituents of the polymer compounds fall under the regulation of REACH. Monomers and polymer additives are registered under REACH. All relevant substances like monomers and polymer additives were successfully registered under REACH before May 31<sup>st</sup>, 2018 to ensure compliance with the legislation.

## **EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)**

Based on (EU) 2015/863 RoHS 3 (amending directive 2011/65/EU) for restriction of the use of certain hazardous substances in electrical and electronic equipment and the information provided to us by our raw material supplier, this product does not contain as intentional ingredients: lead, mercury, cadmium, hexavalent chromium, or their compounds; polybrominated biphenyls (PBB), or polybrominated diphenyl ethers (PBDE). The analysis of the heavy metals, brominated substances and phthalates found listed in Annex II of the RoHS directive is not part of their production process on a routine basis and no actual values can be provided.

## **China ROHS2**

This material complies with Directive 2011/65/EU and China's Management measures for the restriction of hazardous substance in Electrical and Electronics products the supplier confirms that based on their manufacturing process and the raw materials used, the substances listed in the Management measures for the restriction of hazardous substance in Electrical and Electronics products and Annex II of the EU Directive are not expected to be present in the above mentioned product in concentrations exceeding the maximum values given.

Polybrominated Biphenyls (PBB) and Polybrominated Diphenylethers (PBDE) in this product, since this includes Pentabromo-diphenylether and Octabromodiphenylether, these products also comply with EU-Directive 203/11/EC and do not contain any Decabromodiphenylether. Therefore it is in accordance with the new decision of EuGh (European court of justice) that forbids the use of Decabromodiphenylethers in polymeric applications.

## **Heavy Metals (ELV Directive 2000/53/EC)**

### **Coalition of Northeastern Governors (CONEG)**

The products conform to the EU Directive 2004/12/EC (revised Directive 94/62/EC on packaging and packaging waste: presence of mercury, lead, cadmium and hexavalent chromium in packaging < 100 ppm) as well as the CONEG-Regulation.

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**European Directive (94/62/EC) Packaging and Packaging Waste  
EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)**

This product is not hazardous according to the regulation 1272/2008/EC: Classification, Labelling and Packaging – CLP as amended and 1999/45/EC as amended. All substances manufactured or imported in quantities between 100 and 1000 tons/year have been registered. Supplier confirms that product does not contain any substances listed in Annex II of this directive (2012/19/EU) as an intentional ingredient. Analysis of the heavy metals and brominated substances listed in Annex II of the RoHS directive is not part of the production process on a routine basis and no actual values can be provided.

**European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)**

This product does not contain BFDGE.

**California Proposition 65  
(Safe Drinking Water and Toxic Enforcement Act of 1986)**

This product complies with the requirements of California Proposition 65 and do not require a warning statement under normal use conditions.

**Conflict Materials (Dodd-Frank Wall Street Reform and Consumer Protection Act)**

The supplier of this product has advised us that this product does not contain conflict minerals (as defined in the applicable SEC rules) who rely upon the conflict minerals inquiries information received from their suppliers.

**Ozone Depleting Chemicals (ODCs)  
Ozone depleting substances; Regulation EU 1005/2009**

Herewith we confirm that the Products by constitution do not contain ozone depleting substances as listed in Annex 1 of EU 1005/2009. The presence of ubiquitous traces cannot be excluded.

**Phthalates**

Phthalates used as softeners, incl. those listed in Annex XIV of EU 1907/2006 (REACH) and in Annex of Directive 2005/84/EC, however; this product does not use phthalate softeners (monomeric organic compounds) in its manufacturing and by constitution do not contain the following substances listed: DEHP (Diethyl hexyl phthalate), DINP (Diisononyl phthalate), DIDP (Diisodecyl phthalate), DBP (Dibutyl phthalate), BBP (Benzylbutyl phthalate), DMEP Bis-(methoxy ethyl)-phthalate, DnPP (Di-n-pentyl phthalate), DNOP (Di-n-octyl phthalate), DiPP (Diisopentyl phthalate), and DIBP (Diiso butyl phthalate).

**Materials from Genetically Modified Organisms**

The supplier does not intentionally use genetically modified organisms (GMO) during manufacturing. However, they do not on a routine basis test the materials used in the



manufacture of the product and do not keep documents from all their raw materials suppliers confirming the absence of GMO materials.

### **Additional Substance Information**

This product is not intentionally manufactured or formulated with the following substances or compounds; however, we do not analyze for these substances or compounds.

2-Mercaptobenzothiazole (MBT)  
Aflatoxin-like compounds  
Azoxy compounds  
Benzyl butyl phthalate (BBP)  
Bis(2-ethylhexyl) Adipate (DEHA)  
Bis(2-Ethylhexyl) phthalate (DEHP)  
Bisphenol compounds, incl. but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ  
Butylated Hydroxyanisole (BHA)  
Butylated Hydroxytoluene (BHT)  
Dibutyl phthalate (DBP)  
Diisobutyl phthalate (DIBP)  
Dioxins and similar compounds  
Endocrine Disruptors (proven by the industry)  
Epoxy Resin  
Halogenated (Brominated or chlorinated) or phosphorous based flame retardants  
Isocyanate  
Melamine  
Natural rubber latex, dry natural rubber, or synthetic latex  
Nitroso compounds  
Nitrosamines  
Novolac Glycidyl Ethers (NOGE)  
Organic phosphates  
Parabens  
Perfluorooctane Sulfonate (PFOS)  
Phthalates / Phthalate esters  
Plasticizers  
Polybrominated Biphenyls (PBB's)  
Polybrominated Diphenyl Ethers (PBDEs)  
Polybrominated Terphenyls (PBTs)  
Polychlorinated Biphenyls (PCBs)  
Polycyclic aromatic hydrocarbon (PAH)  
Polyurethane  
Polyvinyl Chloride (PVC)  
Polyvinylidene Chloride (PVDC)

### **Sterilization Methods**

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E-beam/Gamma	N/A.
EtO	Acceptable.
Autoclave	Steam or Dry heat is acceptable.

### **Shelf Life and Expiration Date**

Eldon James has tight controls on inventory, so finished products are manufactured and sold quickly. Consequently, raw materials are stored for a relatively short time before use in the manufacturing process. Eldon James cannot commit to a shelf life on products, but we stand by the quality and use of new raw materials. Resin manufacturers usually make no commitment on shelf life. Eldon James does not make any claims regarding Expiration Date because our customers use our products in many different applications and conditions. Eldon James cannot make any assessment or claims regarding expiration. Each individual condition and application must be tested by the customer to determine the limits of each product, material, and use.

### **Use of this Regulatory Information Data Sheet**

The information provided as requested is intended to be used for informational purposes only. The information is provided on a without prejudice basis and should not be viewed as giving technical advice, instruction, or otherwise. The information is furnished free of charge and is based on supplier knowledge and understanding. Eldon James Corporation makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of any compound under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.