



**Amcort Flexibles North America, Inc.**  
**Regulatory Affairs**  
Neenah Innovation Center  
2301 Industrial Drive  
Neenah, WI 54956  
USA

## Declaration of Regulatory Compliance

### **Amcort® Parafilm® Laboratory Film**

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*Zachary L. Porior*

9 September 2025

Zachary Porior, Regulatory Affairs Specialist

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#### **USA FOOD CONTACT COMPLIANCE**

**Statement on  
regulatory  
compliance**

This product is manufactured in compliance with all applicable regulations set forth in 21 CFR §§ 174 – 186.

**Continuing  
Guarantee**

For the purpose of Section 303(c)(2) of the Federal Food, Drug and Cosmetic Act and any applicable food additive regulation, and for no other purpose, Amcor Flexibles North America, Inc., as seller, hereby guarantees that all products sold to your company are not, when shipped, adulterated or misbranded within the meaning of the act and regulations promulgated thereunder. Seller further guarantees that as of the date of each shipment, no such article is an article which cannot be introduced into interstate commerce, under the provisions of Section 404, 505, or 512 of the act. Civil liability, if any, shall be determined solely by seller's general terms and conditions of sale applicable to sales of all product by seller. This Guarantee is continuing and shall remain in full force and effect until revoked by the seller in writing. Notice of acceptance of this Guarantee is hereby waived. Any notice transmitted to the buyer at its place of business shall be sufficient compliance with the requirements hereof.

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**Limitation on use**

This product has the following food type and temperature limitations as outlined in Table 1 & Table 2 of 21 CFR 176:

Non-food use

The brand-owner has final responsibility to determine fitness of use with the intended food product.

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| <b>Statement on good manufacturing practice</b> | 21 CFR § 174.5 sets forth the general provisions on good manufacturing practices applicable to indirect food additives, of which Amcor products comply. Food processors may use this product to meet their safety and suitability obligations under 21 CFR § 117.80 (a)(2) if the food type and temperature limitations are observed. This compliance statement is also based upon the manufacturing facilities' adherence to good manufacturing practices consistent with Food, Drug and Cosmetic Act as amended. |
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## **FREQUENTLY ASKED REGULATORY MATTERS**

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| <b>Prop 65</b>      | This product complies with the California Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65. A warning label is not required on the basis that there is no exposure to any Proposition 65 substances in the reasonably anticipated uses.                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>REACH</b>        | Concerning Regulation (EC) No. 1907/2006, commonly known as REACH, a) Amcor products are compliant with obligations under REACH; b) As delivered, Amcor products are classified as articles and are exempt from registration requirements; c) Amcor products do not have reportable substances of very high concern (SVHC); and d) Amcor products comply with Annex XVII restrictions.                                                                                                                                                                                                                                                                                                                 |
| <b>SVHC</b>         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Annex XVII</b>   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Heavy Metals</b> | Amcor products comply with Toxics in Packaging Clearing House model legislations (TPCH, originally drafted by CONEG) and European Union Directive 94/62/EC, in that a) lead, cadmium, mercury and hexavalent chromium are not intentionally used in the manufacturing of Amcor products and b) the total incidental level of the metals in the final Amcor product is below 100 ppm.                                                                                                                                                                                                                                                                                                                   |
| <b>TPCH/CONEG</b>   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>94/62/EC</b>     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>RoHS 3</b>       | <p>This product meets the maximum concentration values (MCV) listed in European Commission Directive 2011/65/EU (RoHS 2), including amendment 2015/863 (aka RoHS 3), restricting the use of certain hazardous substances in each of the homogeneous material in electrical and electronic equipment (EEE) as follows:</p> <ul style="list-style-type: none"> <li>• Less than 0.1% by weight for lead, mercury and hexavalent chromium</li> <li>• Less than 0.1% by weight for polybromo biphenyls (PBB) and polybrominated biphenyl ethers (PBDE)</li> <li>• Less than 0.01% by weight for cadmium</li> <li>• Less than 0.1% by weight for phthalates, including DEHP, BBP, DBP, &amp; DIBP</li> </ul> |

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| <b>Conflict Minerals</b>         | Pursuant to Security and Exchange Commission’s guidance published on May 30, 2013, packaging material is outside the scope of the Conflict Mineral regulations and does not need to be considered for reporting purposes. Nevertheless, Amcor products do not contain Conflict Minerals (columbite-tantalite, cassiterite, wolframite, and gold as identified in Public Law 111-203 or their derivatives tantalum, tin, and tungsten, as enumerated in 77 Federal Register 56273 at 56285).                                                                                                                                                           |
| <b>Food Allergens</b>            | Amcor products are not edible food or food ingredients subject to the Food Allergen Labeling and Consumer Protection Act (FALCPA) or Regulation (EU) No 1169/2011. Nevertheless, they do not contain or come into contact with the following food allergens or proteins thereof: milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, soy beans, cereals containing gluten, celery, mustard, cotton seeds, poppy seeds, sesame seeds, sunflower seeds, Sulphur dioxide and sulphites, mollusks, and lupin. Additionally, other known sources of food allergens, such as monosodium glutamate, yellow #5, and buckwheat are not present. |
| <b>SDS</b>                       | Amcor products are considered non-hazardous articles and are not subject to the requirement of Safety Data Sheets in accordance with OSHA Hazard Communication Standard (29 CFR 1910.1200), European Union Regulation (EC) No. 1272/2008, and other similar regulations worldwide.                                                                                                                                                                                                                                                                                                                                                                    |
| <b>ADDITIONAL INFORMATION</b>    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Natural Rubber Latex</b>      | This product is not manufactured with Natural Rubber Latex.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Material of Animal Origin</b> | This product does not contain a material of animal origin.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Phthalates</b>                | Amcor Flexibles North America products are not intentionally formulated with ortho-phthalates. Our products are in compliance with amended CFR Title 21 - Federal Register 31080 published on May 20th, 2022 & with the state of Maine legislation H.P 1043 – L.D. 1433 effective January 1 <sup>st</sup> , 2022, pertaining to ortho-phthalates.                                                                                                                                                                                                                                                                                                     |
| <b>Starch</b>                    | The white-powdery substance, which may be found on the surface of food contact packaging articles, is a food-grade starch that is used to facilitate the food packaging operation and does not have a technical effect on the food as consumed. Such use of starch falls within the scope of processing aid as defined in 21 CFR 170.3 (o) and no ingredient labeling is required in accordance with 21 CFR 101.100 (a)(3)(iii).                                                                                                                                                                                                                      |

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| <b>Canada</b>                     | <p>This product, when used as intended, meets the safety standards set forth in Division 23 of the Food and Drugs Act and Regulations since outlined Canada regulations are similar to US FDA Title 21 regulations.</p> <p>Canada LONO – As of July 2014, Letter Of No Objection (LONO) is not needed for packaging materials.</p>                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Food Facility Registration</b> | <p>Facilities that manufacture Amcor products comply with regulations promulgated under section 415 of the Federal Food, Drug and Cosmetic Act, as amended by Title III, subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, i.e. the Bioterrorism Act of 2002, and as amended by Title III of the FDA Food Safety Modernization Act of 2011. Pursuant to section 21 CFR 1.227), 1.230(a) and FDA “Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)” published by FDA in August 2018), facility that manufacturers/processes food contact substances including food packaging are exempt from registration requirements.</p>     |
| <b>Substances of interest</b>     | <p>This product is not intentionally formulated with the following substances:</p> <ul style="list-style-type: none"> <li>Bisphenol A (BPA)</li> <li>Bisphenol F (BPF)</li> <li>Bisphenol S (BPS)</li> <li>Class I &amp; II ozone depleting substances</li> <li>Melamine</li> <li>Azo compounds</li> <li>Radiological substances</li> <li>Perchlorates</li> <li>Engineered Nano Materials &amp; Technology</li> <li>Genetically Modified Organisms (GMO's)</li> <li>Genetically Engineered Materials</li> <li>Fungicides</li> <li>Pesticides</li> <li>1,4-Dioxane</li> <li>PFAS (Perfluoroalkyl and polyfluoroalkyl substances)</li> </ul> <p>We have not conducted any tests to determine the presence of these substances.</p> |