Amcor Flexibles North America, Inc.
Regulatory Affairs
Neenah Innovation Center
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USA

Declaration of Regulatory Compliance

Amcor® Parafilm® Laboratory Film

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9 September 2025

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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.
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.

Statement on good manufacturing practice	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.

FREQUENTLY ASKED REGULATORY MATTERS

Prop 65	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.
REACH **SVHC** **Annex XVII**	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.
Heavy Metals **TPCH/CONEG** **94/62/EC**	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.
RoHS 3	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: • Less than 0.1% by weight for lead, mercury and hexavalent chromium • Less than 0.1% by weight for polybromo biphenyls (PBB) and polybrominated biphenyl ethers (PBDE) • Less than 0.01% by weight for cadmium • Less than 0.1% by weight for phthalates, including DEHP, BBP, DBP, & DIBP

Conflict Minerals	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).
Food Allergens	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.
SDS	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.

ADDITIONAL INFORMATION

Natural Rubber Latex	This product is not manufactured with Natural Rubber Latex.
Material of Animal Origin	This product does not contain a material of animal origin.
Phthalates	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 1st, 2022, pertaining to ortho-phthalates.
Starch	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).

Canada	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. Canada LONO – As of July 2014, Letter Of No Objection (LONO) is not needed for packaging materials.
Food Facility Registration	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.
Substances of interest	This product is not intentionally formulated with the following substances: Bisphenol A (BPA) Bisphenol F (BPF) Bisphenol S (BPS) Class I & II ozone depleting substances Melamine Azo compounds Radiological substances Perchlorates Engineered Nano Materials & Technology Genetically Modified Organisms (GMO's) Genetically Engineered Materials Fungicides Pesticides 1,4-Dioxane PFAS (Perfluoroalkyl and polyfluoroalkyl substances) We have not conducted any tests to determine the presence of these substances.