PRI Plus

Regulatory Status

Roll Label Constructions

PRI Plus | www.PRIplus.com | (800) 813-8907 | 608 Rye Beach Rd, Huron, Ohio 44870

Revision: 01.009 | February 2025

Contents

This Regulatory Document is for general information regarding common regulatory questions. PRI Plus will update this document to keep up with current regulations, status, and standards. The information found within this document is based on supplier information, formulation, and manufacturing practices. PRI Plus does not conduct testing to determine suitability nor does it require testing to be carried out by its suppliers. The determination of the suitability of the final use of the products is the sole responsibility of the customer. For more information, please contact your PRI Plus customer support representative.

Product Identification

Product Classification

PRI Plus Roll Label Constructions are considered **Articles** as defined by the Federal Occupational Safety and Health Administration (OSHA).

According to OSHA's Hazard Communication Standard [29 CFR 1910.1200 (c)]:

Article means a manufactured item other than a fluid or particle:

- *(i) which is formed to a specific shape or design during manufacture;*
- *(ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and*
- *(iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical and does not pose a physical hazard or health risk to employees.*

Safety Data Sheets

According to 29 CFR 1910.1200(b)(6)(v), the section *1910.1200- Hazard Communication* does not apply to articles. Thus, PRI Plus Roll Label Constructions are exempt from the Safety Data Sheets (SDS) provisions.

United States Regulations

Chemical Substances Undergoing Prioritization: High Priority

Twenty chemical substances have been designated by the EPA as a high priority for upcoming risk evaluations. Nineteen of these twenty substances are not used in the manufacture of PRI Plus Roll Label Constructions. Butadiene is used as a starting material for a rubber in some rubber-based adhesives. It is anticipated that after processing from the supplier, butadiene is present in negligible amounts.

Consumer Product Safety Improvement Act

PRI Plus Roll Label Constructions meet the safety requirements for lead and phthalates in the Consumer Product Safety Improvement Act (CPSIA) of 2008 for children's products. A General Conformity Certificate is not required.

Federal Hazardous Substances Act

To the best of our knowledge and belief, based on tests conducted by us or our suppliers, the adhesive used in PRI Plus Roll Label Constructions is not considered a primary irritant to the skin or eyes, as defined in the Federal Hazardous Substances Act (16 CFR 1500.3(c)(4) and 16 CFR 1500.3 (c)(2)(i)).

PRI Plus also represents, to the best of our knowledge and belief, that the adhesive in the product is not toxic by oral ingestion per the standards set forth in the Federal Hazardous Substances Act (16 CFR 1500.3 (c)(2)(i).

Indirect Food Contact- 21 CFR 175.105

This product meets the standards set by the FDA to comply with Indirect Food Contact.

There are no Fluorinated Surfactant Agents (FSA) in any PRI Plus adhesive products.

The end-user is responsible for determining the applicability of the FDA requirements for the intended use(s) for full compliance with 21 CFR 175.105- Adhesives. This section requires the

adhesive is either separated from food by a functional barrier or used subject to the following limitations:

- *In dry food. The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.*
- *In fatty and aqueous food,, the quantity of adhesive that contacts packaged fatty and aqueous food shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.*

Proposition 65

PRI Plus does not intentionally add any of the toxic chemicals listed pursuant to the California Safe Drinking Water and Toxic Enforcement Act of 1986 as known to cause cancer or reproductive toxicity (sometimes referred to as "California Proposition 65"). We further represent that, to the best of our knowledge and belief, the products do not contain levels of the listed chemicals in amounts and form that would pose a significant risk to any individual who might be exposed to the products under normal conditions of use.

Toxic Substances Control Act (TSCA)

This is to advise you that PRI Plus does not add any persistent, bioaccumulate, toxic chemicals (PBTs), including Decabromodiphenyl ether (DecaBDE); Phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP); Hexachlorobutadiene (HCBD); Pentachlorothiophenol (PCTP) in the Roll Label Constructions.

We can further advise you that our raw material suppliers have represented to us that they do not intentionally add any of these PBTs to the raw materials they supply to us for incorporation into the products.

Toxics in Packaging (formerly CONEG)

PRI Plus does not intentionally add to the product any of the following heavy metals or their compounds: cadmium, hexavalent chromium, lead, and mercury. And though we have not analyzed this product specifically for these substances, based on our knowledge of the raw materials and the manufacturing process, we expect that the sum of any trace quantities is below the legislation limit of 100 ppm.

Uyghur Forced Labor Prevention Act

PRI Plus does not source raw materials from companies or persons located in the Xinjiang Uyghur Autonomous Region (XUAR) pursuant to the Uyghur Forced Labor Prevention Act of 2021.

Volatile Organic Compounds (VOC's)

100% solids are used to coat PRI Plus Roll Label Constructions without the use of solvents. Any residual monomers are expected to be extensively removed during the coating and drying process. PRI Plus does not routinely test for VOC's.

European Union Regulations

EU Regulation 2017/745 on Medical Devices (MDR)

PRI Plus hereby represents that we do not intentionally add any of the chemicals listed pursuant to the EU 2017/745, Annex I, Chapter II, Section 10.4.1 regulation for medical devices. We further represent that, to the best of our knowledge and belief, the products do not contain levels of the listed chemicals in amounts and form that would pose a significant risk to any individual who might be exposed to the products under normal conditions of use. Our products are considered to be "articles" as defined by ECHA, and as such, do not release or otherwise result in exposure to hazardous chemicals under the conditions of intended use.

EU Persistent Organic Pollutants (POPS)

PRI Plus does not intentionally add any of the twelve initial POPs listed in Annexes A, B, or C, any of the nine new POPs added in May 2009, the one POP added in May 2011, the one POP added in April 2013, the three POPs adopted in May 2015, the three POPs added in May 2017, or the two POPs added in May 2019 to the product during our manufacturing process.

Further, we have inquired of our major raw material suppliers, and they have represented to us that they do not intentionally add any of the POPs mentioned previously to the raw materials they supply us for use in the manufacture of the products.

Finally, based on their review of applicable SDSs and certificates of compliance they have received from their suppliers, they do not believe the raw materials they use to manufacture the products they supply to us contain any of the POPs mentioned previously.

Based on the foregoing, and all information otherwise available to us, we further represent that we have no reason to believe that any of the POPs mentioned previously are present in the products in concentrations in excess of incidental amounts.

Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)

Agency effective as of February 07, 2025 (the "SVHCs")
Under EU Regulation (EC) No. 1907/2006 Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH"), and specifically, whether these products contain any of the Substances of Very High Concern identified by the European Chemicals- PRI Plus represents to you the following:

1. We do not intentionally add to the products any of the SVCHs;
2. We have inquired of our major raw material suppliers and, based on the representations they have made regarding the raw materials they supply to us for use in our manufacture of the products, we have no reason to believe that any of the SVHCs is present in excess of 0.1% w/w.

Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS)

The following statements are related to the European Union's January 27, 2003, Directives governing the restriction of the use of certain Hazardous Substances in electrical and electronic equipment, as amended June 8, 2011 (2011/65/EU-RoHS2), and again in 2015 (2015/863/EURoHS3), and Waste Electrical and Electronic Equipment (2002/96/EC-WEEE) (collectively referred to as the "Directives"). We confirm that PRI Plus:

1. does not knowingly incorporate or use the Restricted Substances in the products;

2. does not knowingly purchase any stock or ingredients which are used in the products that contain the Restricted Substances; and,

3. has received representations from our suppliers, based upon their review of raw material composition and applicable SDSs, that they do not intentionally or knowingly incorporate the Restricted Substances in the ingredients they provide to us that are incorporated in the products. Based on the above, we believe that the products meet the RoHS3 and WEEE compliance standards.

Biocidal Product Regulations, BPR, Regulation (EU) 528/2012

In the development and manufacturing of our adhesive products, PRI Plus may incorporate a range of proprietary additives, which could include biocides, to enhance product performance and durability. Whether or not biocides are present in any given formulation, we ensure that all our products are fully compliant with the European Union Biocidal Products Regulation (EU BPR).

Due to the proprietary nature of our formulations, we do not disclose specific details regarding the presence or concentration of biocides. However, we assure our customers that all additives used in our products meet the highest standards of safety and environmental compliance.

Public Interest

BSE / TSE

PRI Plus Roll Label Constructions use adhesives that are 100% free from animal sourced rubber and present no risk of exposure to Bovine Spongiform Encephalopathy / Transmissible Spongiform Encephalopathy (BSE / TSE).

Conflict Minerals

This is to advise you that PRI Plus does not add any of the Conflict Minerals [cassiterite, columbite-tantalite, gold, and wolframite (Public Law 111-203)] and their derivatives [tantalum, tin, and tungsten (77 Federal Register 56273 and 56285)] to the products during our manufacturing process. We also confirm that our suppliers have represented to us that they do not intentionally add any of these minerals to the raw materials they supply to us. PRI Plus and our suppliers do not routinely test for the presence of these minerals, however.

PFOA, PFAS, and PFOS

This is to advise you that PRI Plus does not add the perfluorochemicals / fluorotelomers perfluorooctanoic acid (PFOA), Per- and polyfluoroalkyl substances (PFAS) and perfluorooctanesulfonic acid (PFOS) to our products during our manufacturing process. We further advise you that our raw material suppliers have represented to us that they do not intentionally add PFOA, PFAS or PFOS to the raw materials they supply to us for incorporation into our products.

While neither PRI Plus nor our suppliers routinely test for the presence of PFAS, PFOA or PFOS, we represent to you that PRI Plus has no other information in our possession that would give us reason to believe that the products contain PFAS, PFOA or PFOS in other than trace amounts.

Nitrosamines and Related Precursors

Our products do not intentionally contain nitrosamines, nor are they added during the manufacturing process. Nitrosamines are not tested for in our products. Our suppliers have represented to us that no amines or amides—substances that could potentially act as precursors to nitrosamine formation under certain conditions—are intentionally included in the raw materials used in our formulations.

While our materials meet FDA guidelines for indirect food contact, this does not guarantee the absence of all amine-based compounds. However, if such compounds are present, they are within the safety thresholds established for indirect food contact by the FDA.

Nitrosamine formation is dependent on external conditions, such as the presence of nitrites in certain environments, and it remains the responsibility of the end-user to ensure the suitability of our products for their specific applications.

Substances of Interest

Some of PRI Plus Roll Label Constructions are formulated using natural rubber and/or natural and synthetic rubber latex. Some products are formulated using chlorinated compounds. For more information regarding these, please contact your customer support representative. PRI Plus Roll Label Constructions are not formulated with the following substances of interest:

- Aromatic amines
- Asbestos or Crystalline Silica
- Azo Dyes
- Benzophenone
- BHT and BHA
- Bisphenol A (BPA)
- Brominated Flame Retardants
- Dimethyl Fumarate
- Dioxins
- Epoxy Derivatives
- Food Material of Food Allergens
- Formaldehyde
- Microplastics
- Ozone Depleting Substances
- Phthalate Plasticizers, including DEHP, DINP, DIDP, DnOP, DnHP, BBP, DBP, DIBP, DCHP
- Polychlorinated Biphenyls (PCBs)
- Short-Chained Chlorinated Paraffins (SCCP)
- Tri Nonyl Phenyl Phosphite (TNPP)
- Cobalt
- Mica

Revisions

01.002 - Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) standard reevaluated
15 June 2023

01.003- Indirect Food Contact 21 CFR 175.105 revised to include statement of lack of FSA in all products.
26 June 2023

01.004- Expanded section: Substances of Interest to include Cobalt, Mica
20 March 2024

01.005- Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) standard reevaluated
25 June 2024

01.006- Added section Biocidal Product Regulations, BPR, Regulation (EU) 528/2012
28 August 2024

01.007- Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) standard reevaluated
15 October 2024

01.008- Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) standard reevaluated,
Added section Nitrosamine and Related Precursors
15 November 2024

01.009- Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) standard reevaluated
07 February 2025