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UPM Raflatac Product Safety & Regulatory Compliance Combined Statement for United States manufactured label stock products.

Product Safety & Regulatory Compliance

In this document, you will find compiled regulatory and legislative information for its United States manufactured products.

Table of Contents

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Scope of Use
UPM Raflatac products are semi-finished, general-purpose articles that are typically intended to be used as a labelling component of various packaging systems.

Technical Information Sheet (TIS)
Please find the most current UPM Raflatac technical information sheet (TIS) document by utilizing the product selector link below.

- Technical Information Sheets (TIS)

Articles
The United States Occupational Safety & Health Administration (OSHA) Hazard Communication Standard located in 29 CFR 1920.1200(c), specifically states that an "article" is defined as, 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". UPM Raflatac products are understood as "articles" in accordance with this regulation.

- Articles

Safety Data Sheets (SDS)
The Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 CFR 1910.1200 also requires that chemical manufacturers and importers prepare safety data sheets (SDS) describing the health and physical hazards of chemical products they produce or import. As stated above, label stock products are articles in accordance with this regulation, and as such, SDS's are not applicable to label stock products.

Toxic Substance Control Act (TSCA) – Chemical Inventory
Raw material components used in the manufacturing process are either listed or exempted from the United States Toxic Substances Control Act (TSCA) chemical inventory.
UPM Raflatac does not intentionally add the substances of concern listed below to its products, and as such, has no reason to suspect these substances to be present in its products.

- Phenol, isopropylated phosphate (3:1) (PIP; CAS RN: 68937-41-7)
- 2,4,6-Tris(tert-butyl) phenol (TTBP; CAS RN: 732-26-3)
- Pentachlorothiophenol (PCTP; CAS RN: 133-49-3)
- Decabromodiphenyl ether (DecaBDE; CAS RN: 1163-19-5)
- Hexachlorobutadiene (HCBD; CAS RN: 87-68-3)

Additionally, TSCA also provides the United States Environmental Protection Agency (EPA) with authority to require reporting, record-keeping and testing requirements, and restrictions related to chemical substances and/or mixtures. UPM Raflatac's products qualify as articles under TSCA which are generally exempt.

Per- and polyfluoroalkyl substances (PFAS)
UPM Raflatac does not intentionally add Per- and polyfluoroalkyl substances (PFAS), specifically, Perfluorooctanoic acid (PFOA; CAS RN: 335-67-1) or Perfluorooctanesulfonic acid (PFOS; CAS RN: 1763-23-1) to its products, and as such, has no reason to suspect these substances are present in its products. Additionally, please note that fluorination is not a direct intentional manufacturing process utilized by UPM Raflatac.

FDA 21 CFR § 110 – Good Manufacturing Practices (GMP)

Good manufacturing practices (GMP) at UPM Raflatac's American based manufacturing facilities is supported by its industry leading Lean Six-Sigma and 5S hygiene program, followed by its third-party certified ISO 9001:2015 – Quality Management System, ISO 14001:2015 Environmental Management, ISO 45000:2018 Health & Safety Management and ISO 22000:2018 Food Safety Management System programs. UPM Raflatac products are intended to be manufactured under applicable hygienic conditions.

Hazard Analysis & Critical Control Points (HACCP)

UPM Raflatac has carried out regional and local HACCP assessments that covers the following hazards for its manufacturing facilities:

- Physical
- Chemical
- Biological
- Allergens

FDA 21 CFR § 175.105 - *Adhesives*

The overall regulatory status of a pressure sensitive label used in food packaging is determined by the regulatory status of each individual substance that comprises the label that is reasonably expected to migrate to food. Individual substances expected to migrate to food should be covered by one of the following:

- a regulation listed in Title 21 Code of Federal Regulations
- a prior sanctioned letter
- meeting the criteria for Generally Recognized as Safe (GRAS) status (including but not limited to a GRAS regulation or GRAS notice)
- a Threshold of Regulation (TOR) exemption request
- or an effective Food Contact Notification (FCN).

UPM Raflatac has surveyed suppliers of components used to formulate its adhesives and verified compliance with the requirements of 21 CFR 175.105(a)(2) – *Adhesives*. For a product specific declaration please contact product safety and regulatory compliance at the email address below.

FDA 21 CFR § 801.437 – User labelling for devices that contain natural rubber

"Latex" is generically defined as "a water emulsion of a synthetic rubber or plastic obtained by polymerization and used especially in coatings (as paint) and adhesives." By this definition, all water based acrylic adhesives could be considered latex. UPM Raflatac's experience is that label end users are typically concerned about the presence of natural rubber latex in label stock adhesives, as natural rubber latex may cause allergic reactions in some people. Please contact the email address listed below for a product specific natural rubber latex declaration.

Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER)

UPM Raflatac does not intentionally add Federal Food, Drug and Cosmetic Act (FD&C Act) listed major food allergens to its label stock products and has no reason to suspect their presence in its products that would require FD&C major food allergen labeling requirements. Please see Federal Food, Drug and Cosmetic Act (FD&C Act) listed major food allergens below:

- Milk
- Egg
- Fish
- Crustacean shellfish
- Tree nuts
- Wheat
- Peanuts
- Soybeans
- Sesame

Wheat/starch

The paper components used to manufacture various label stock products may contain residual amounts of corn starch that may be used as fillers further up the supply chain during the paper making process. UPM Raflatac does not intentionally add these substances to its products, nor are they stored or processed at its manufacturing facilities.

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

The California Safe Drinking Water and Toxic Enforcement Act of 1986, otherwise known as Prop 65, is a risk-based regulation that requires a consumer warning for the potential exposure to a listed substance. Prop 65 risk assessments are product specific. Prop 65 assessments are addressed on a case-by-case basis. Please contact product safety and regulatory compliance at the email address listed below for a product specific Prop 65 assessment. For more information related to Prop 65 listed substances, please see additional link below.

- The Proposition 65 List - OEHHA (ca.gov)

Consumer Product Safety Improvement Act (CPSIA) of 2008 – phthalates

UPM Raflatac does not intentionally add the phthalates listed below to its products, and as such, has no reason to suspect their presence in most of its products above the 0.1% w/w threshold referenced in the Consumer Product Safety Improvement Act (CPSIA) of 2008. Please contact email UPM Raflatac for more information on specialty grade products with respect to CPSIA.

- Di-(2-ethylhexyl) phthalate — DEHP; CAS RN: 117-81-7
- Dibutyl phthalate — DBP; CAS RN: 84-74-2
- Benzylbutyl phthalate — BBP; CAS RN: 85-68-7
- Diisononyl phthalate — DINP; CAS RN: 28553-12-0
- Diisobutyl phthalate — DIBP; CAS RN: 84-69-5
- Di-*n*-pentyl phthalate — DPENP; CAS RN: 131-18-0
- Di-*n*-hexyl phthalate — DHEXP; CAS RN: 84-75-3
- Dicyclohexyl phthalate — DCHP; CAS RN: 84-61-7

Dodd-Frank Wall Street Reform Act – Conflict Minerals

In accordance with section 1502(e)(4) of the Dodd-Frank Wall Street Reform Act, we understand conflict minerals are defined as (A) columbite-tantalite, also known as coltan (the metal ore from which tantalum is extracted); cassiterite (the metal ore from which tin is extracted); gold; wolframite (the metal ore from which tungsten is extracted); or their derivatives; or (B) any other mineral or its derivatives determined by the Secretary of State to be financing conflict in the Democratic Republic of the Congo (DRC) or an adjoining country. Please contact product safety and regulatory compliance at the email address below for a product specific declaration.

Federal Hazardous Substance Act (FHSA) – sensitizing substances

UPM Raflatac does not intentionally add “strong sensitizer” substances as listed in 16 CFR 1500.13 to its products and has no reason to suspect their presence in its products.

REACH EU Regulation (EC) No 1907/2006

REACH Candidate List of Substances of Very High Concern (SVHC) was updated **January 21, 2025**. Article 33 of Registration, Evaluation and Authorization of Chemicals (REACH) obligates article suppliers to provide relevant information about the presence of substances included on the Candidate List of SVHCs (at concentrations greater than 0.1% w/w) in their products to recipients of these articles. Please note that REACH SVHC assessments are product specific. REACH SVHC assessments are addressed on a case-by-case basis. For a current product specific REACH SVHC declaration, please contact product safety and regulatory compliance at the email address below. For the current list of REACH SVHC substances, please see the REACH SVHC list link below.

- Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

EU Directive 2011/65/EU – Restriction of Hazardous Substances (RoHS/RoHS2/RoHS3)

UPM Raflatac does not intentionally add the RoHS listed substances below to its products and has no reason to suspect that these substances are present in our products at levels above the allowable regulatory values. For a product specific RoHS declaration, please contact product safety and regulatory compliance at the email address below.

- Lead 0.1%
- Mercury 0.1%
- Cadmium 0.01%
- Hexavalent chromium 0.1%
- Polybrominated biphenyls (PBB's) 0.1%
- Polybrominated diphenyl ethers (PBDE's) 0.1%
- Bis(2-ethylhexyl) phthalate (DEHP) 0.1%
- Benzylbutyl phthalate (BBP) 0.1%
- Dibutyl phthalate (DBP) 0.1%
- Diisobutyl phthalate (DIBP) 0.1%

The statements provided in this correspondence is based on knowledge of label stock processing and raw materials, review of available safety data sheets, and statements from component suppliers for its products. Please note that no laboratory analysis has been performed to confirm the absence or presence of any of the substances referenced for this inquiry in its products. Customers and end users should note that further processing and converting of UPM Raflatac products must be assessed by the downstream users of the products and are responsible for their own determination for the suitability of their products for their desired end use applications. Furthermore, it is noted that supply chain information currently available is not comprehensive for all raw materials used in its manufacturing processes and that collecting information from the raw material supply chain is an on-going activity that may prompt revision of this information without notice.

Please contact (828) 651-4800 or americas.support@upmraflatac.com if there are any questions.

Revision History

Date	Comment
2023-09-06	Published combined statement.
2023-09-07	Revised FALCPA of 2002 to FASTER of 2021.
2024-02-14	Updated the REACH statement.
2024-07-08	Updated the REACH statement, Updated the Natural rubber latex statement.
2024-11-26	Updated the REACH statement.
2025-01-22	Updated the REACH statement.