



Intelligent Stewardship™



FDA Approval Regulations

T-PRO® 550

Lithic Industries® provides sophisticated polymer emulsions engineered with a focus on durability and sustainability. The versatile polymer offers both temporary and permanent solutions for a wide range of soil engineering projects.

The **Lithic Material T-Pro® 550** polymer is fully compliant with FDA and EU regulations, guaranteeing its safety for all forms of life. Below represents a detailed overview of regulatory approvals and coverage.

UNITED STATES FOOD AND DRUG ADMINISTRATION

When used unmodified for food contact applications, the composition of this product will comply with the U.S. Food, Drug, and Cosmetic Act as amended under Food Additive Regulations:

U.S. FDA 21 CFR 175.105 (Adhesives)

U.S. FDA 21 CFR 176.170(b)* (Components of paper and paperboard in contact with aqueous and fatty foods)

U.S. FDA 21 CFR 176.180 (Components of paper and paperboard in contact with dry foods)

Lithic Material T-Pro® 550 complies with 21 CFR 176.170, Components of Paper and Paperboard in Contact with Aqueous and Fatty Foods provided that the food contact surface of the paper and paperboard complies with the extractives limitations in 21 CFR 176.170 paragraph (c).

**This regulation has two separate listings of materials, paragraph (a) or paragraph (b). Materials that are listed in paragraph (b) may be used in paper, but the final food contact surface is subject to the extraction tests, also referred to as end tests.*

Lithic Material T-Pro® 550 does not have any limitations regarding food types and conditions of use as referred to in 21 CFR 176.170(c).



SPECIFIC LIMITATIONS / RESTRICTIONS

The following specific migration limits and application limitations apply to XZ 97365.00 Experimental Binder under FDA:

3:1 Blend of 5-Chloro-2-methyl-4-isothiazolin-3-one / 2-Methyl-4-isothiazolin-3-one for use only:

1. As an antimicrobial agent for polymer latex emulsions in paper coatings at a level not to exceed 50 parts per million (based on Isothiazolone active ingredients) in the coating formulation.
2. As an antimicrobial agent for finished coating formulations and for additives used in the manufacture of paper and paperboard, including fillers, binders, pigment slurries and sizing solutions at a level not exceeding 25 parts per million (based on additives).

2-Bromo-2-nitro-1,3-propanediol: For use only as an antimicrobial/preservative in fillers, pigment slurries, starch sizing solutions, and latex coatings at levels not to exceed 0.01 percent by weight of those components.

1,2-Benzisothiazolin-3-one: For use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.01 mg/in² (0.0016 mg/cm²) of the finished paper and paperboard.

EU REGULATION (EC) NO 1935/2004

In reference to Article 3 of Regulation (EC) No 1935/2004 concerning the generic product safety requirements of materials and articles intended to come into contact with foodstuffs:

- The Trinseo™ latex plants manufacturing Lithic Material T-Pro® 550 are certified that their Quality Management System had been approved to the ISO 9001 Quality Management System Standards.
- Lithic Material T-Pro® 550 is manufactured in accordance with good manufacturing practice as outlined in Commission Regulation (EC) No 2023/2006.
- The raw materials used in the manufacturing of Lithic Material T-Pro® 550 are of a suitable purity for articles intended for use in contact with foodstuffs. However, good manufacturing practice needs to be applied during processing of the product, including adherence to the maximum recommended processing temperatures.

EU REGULATION (EC) NO 1935/2004 (continued)

- All monomers and additives used in the manufacturing of Lithic Material T-Pro® 550 are listed or referenced in BfR Recommendation XIV (A), BfR XXXVI or (EC) Regulation 10/2011.
- Trinseo™ does not perform organoleptical tests on articles produced from Lithic Material T-Pro® 550 on a routine basis. Please note that it is the responsibility of the manufacturers of the finished food-contact article and/or the industrial packers to ensure that the article in its final application does not bring about a deterioration of the organoleptical characteristics of the foodstuff.
- Parameters such as applied processing conditions and any modification of Lithic Material T-Pro® 550 is beyond the control of Trinseo™.
- Systems and procedures are implemented in the manufacture of Lithic Material T-Pro® 550 in order to fulfill the requirements of Article 17 of Regulation (EC) No 1935/2004 regarding traceability.

COMMISSION REGULATION (EU) NO 10/2011 ON PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFF AND ITS SUBSEQUENT AMENDMENTS

All monomers used in the manufacture of Lithic Material LLC T-Pro® 550 are listed in the Commission Regulation (EU) 10/2011 and its subsequent amendments.

RESTRICTIONS

Acrylic Acid: A Specific Migration Limit (SML)(T) of 6 mg/kg applies, meaning that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as FCM substance No's: 70, 147, 176, 218, 323, 325, 365, 371, 380, 425, 446, 448, 456, and 636. From these mentioned substances only acrylic acid (FCM substance No: 147) is used in the manufacture of Lithic Material T-Pro® 550.

Based on data obtained on similar Trinseo™ Binder products, the level of residual acrylic acid (CAS No. 79-10-7) in Lithic Material T-Pro® 550 is expected to be less than 1,200 ppm, based on wet latex weight.

Butadiene (CAS No. 106-99-0): Maximum permitted quantity of the "residual" substance in the material or article: 1 mg/kg. Specific Migration Limit (SML) in food or food stimulant: Not detectable mg/kg. Detection limit of the Method of Analysis: 0.01 mg/kg (FCM substance No: 223).

Based on data obtained on similar Trinseo™ Binder products, the level of residual butadiene in Lithic Material T-Pro® 550 is below the detection limit of 0.1 ppm based on wet latex weight. Please note that we do not routinely analyze Lithic Material T-Pro® 550 for residual butadiene.

Sodium Monoalkyl Dialkylphenoxybenzenedisulphonate: A Specific Migration Limit (SML) of 9 mg/kg food applies (FCM substance No: 88). The level of Sodium monoalkyl dialkylphenoxybenzenedisulphonate in Lithic Material T-Pro® 550 is less than 0.3% based on wet latex weight.

Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C 8 - C 22) alcohols: A Specific Migration Limit (SML) of 1.8 mg/kg food applies (FCM substance No: 799). The level of Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C 8 - C 22) alcohols in Lithic Material T-Pro® 550 is less than 0.005% based on wet latex weight.

Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstock: A Specific Migration Limit (SML) of 0.05 mg/kg and the restriction "**Not to be used for articles in contact with fatty foods for which simulant D1 and/or simulant D2 is laid down.**" (FCM substance No: 93) applies. The level of paraffinic waxes in Lithic Material T-Pro® 550 is less than 0.085% based on wet latex weight.



COMMISSION REGULATION (EU) NO 10/2011 ON PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFF AND ITS SUBSEQUENT AMENDMENTS *(continued)*

2-Methyl-4-isothiazolin-3-one (CAS No.: 2682-20-4): A Specific Migration Limit (SML) of 0.5 mg/kg food applies (FCM substance No: 451). Only to be used in aqueous polymer dispersions and emulsions and at concentrations which do not result in an antimicrobial effect at the surface of the polymer or on the food itself. The level of 2-Methyl-4-isothiazolin-3-one in Lithic Material T-Pro® 550 is less than 0.0006% based on wet latex weight.

1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS No.: 4080-31-3): A Specific Migration Limit (SML) of 0.3 mg/kg food applies (FCM substance No: 474). The level of 2-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride in Lithic Material T-Pro® 550 is less than 0.0002% based on wet latex weight.

Some of the components (biocides, emulsifiers, initiators) in the manufacture of Lithic Material T-Pro® 550 are not listed in the Commission Regulation (EU) 10/2011 and its subsequent amendments but e.g. in BfR XIV (A).

BfR

The composition of Lithic Material T-Pro® 550, if used, both unmodified and in accordance with good manufacturing practices for food contact applications, will comply with the following:

German Recommendations of the “Kunststoffkommission” des Bundesinstitutes für Risikobewertung (BfR)

XIV Part A Polymer-Dispersionen (as of 01 April 2022)

XXXVI Papiere, Kartons und Pappen für den Lebensmittelkontakt (Paper and board for food contact) (as of 01 February 2023)



SPECIFIC LIMITATIONS / RESTRICTIONS

The following specific migration limits and application limitations apply to Lithic Material T-Pro® 550 under BfR and/or Regulation (EC) 10/2011:

Monomers	
Acrylic Acid	<p>A Specific Migration Limit (SML)(T) of 6 mg/kg applies, meaning that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as FCM substance No's: 70, 147, 176, 218, 323, 325, 365, 371, 380, 425, 446, 448, 456, and 636. From these mentioned substances only acrylic acid (FCM substance No: 147) and n-Butyl acrylate (FCM substance No: 325) are used in the manufacture of Lithic Material T-Pro® 550.</p> <p>Based on data obtained on similar Trinseo™ Binder products, the level of residual acrylic acid (CAS No. 79-10-7) in Lithic Material T-Pro® 550 is expected to be less than 1,200 ppm, based on wet latex weight.</p>
Butadiene	<p>Maximum permitted quantity of the "residual" substance in the material or article: 1 mg/kg.</p> <p>Specific migration limit in food or food stimulant: Not detectable mg/kg. Detection limit of the Method of Analysis: 0.01 mg/kg (Limitation in BfR XIV).</p> <p>Based on data obtained on similar Trinseo™ Binder products is the level of residual butadiene in Lithic Material T-Pro® 550 below the detection limit of 0.1 ppm based on wet latex weight. Please note that we therefore do not routinely analyze Trinseo™ Binder products for residual butadiene.</p>
Biocides	
	<p>Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one (ca. 3 parts) and 2-Methyl-4-isothiazolin-3-one (ca. 1 part): in total max. 0.004 mg /dm² in dispersion film (Limitation in BfR XIV).</p> <p>2-Bromo-2-nitro-propanediol-(1,3): max. 0.032 mg active ingredient/dm² in dispersion film, this substance must not be detectable in extract of the finished product. (Limitation in BfR XIV).</p> <p>Impurity from raw materials: 1,2-Benzisothiazolin-3-one: max. 0.08 mg active ingredient/dm² dispersion film (Limitation in BfR XIV).</p>

SPECIFIC LIMITATIONS / RESTRICTIONS (continued)

Emulsifiers	
	<p>Under conditions of use, not more than 5 mg/dm² emulsifier is allowed to migrate from the final product. The amount of emulsifiers (various types) used in the manufacture of Lithic Material T-Pro® 550 is less than 1.6% based on wet latex weight.</p> <p>Alkyloxyethylate: SML = 5 mg/dm²; < 0.6% in the wet latex per regulation (EC) 10/2011, the following restrictions apply:</p> <p>FCM substance No: 88 SML = 5mg/kg < 0.3% in the wet latex. FCM substance No: 799 SML = 1.8 mg/kg < 0.005 % in the wet latex.</p>
Paraffinic Wax	
	<p>A Specific Migration Limit (SML) of 0.05 mg/kg and the restriction “Not to be used for articles in contact with fatty foods for which simulant D1 and/or simulant D2 is laid down.” (FCM substance No: 93) applies. The level of paraffinic wax in Lithic Material T-Pro® 550 is less than 0.085% based on wet latex weight.</p>

DISCLAIMER

The uses cited above are subject to good manufacturing practices and any limitations, which are part of the regulations. Please note that it is the responsibility of both the manufacturer of finished food contact articles as well as the industrial food packers to make sure that such articles and their actual use are followed and conform to all applicable regulations, including those regarding overall migration. The regulations should be consulted for complete details and for any changes or amendments.

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The Lithic Material T-Pro® 550 polymer is manufactured in partnership with Trinseo™ PLC.

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18 S. Main, Suite 919, Temple, Texas, 76501 USA

+1.254.314.8656 | info@lithicindustries.com | lithicindustries.com