

Versatex Building Products LLC, Inc.

FDA Food Contact Compliance Review of Versatex Building Products LLC.'s Signboard

Prepared by: Nick Jermstad, Manager of Toxicology & Environmental Assessment

Date: June 23, 2016

Introduction

Versatex Building Products LLC. (“Versatex”) has requested an FDA food contact compliance review of its signboard that may be used in a food facility. The product would be used as signboard or display board in the graphics market.

Intertek completed a FDA review of the components of the signboard. Where a full composition was not available, supplier statements and/or safety data was applied.

FDA Compliance Review

Intertek has reviewed the aforementioned products and a summary of the FDA compliance review is provided here:

RM	RM%	Substance Name	CAS#	% in RM	% in Product	FDA Approval
PVC Resin	79.21%	Polyvinyl Chloride	9002-86-2	100%	79.21%	21 CFR 177.1010 - Acrylic and modified acrylic plastics, semirigid and rigid
Omya CaCO3	6.34%	Limestone	1317-65-3	97%	6.15%	21 CFR 184.1409 - GRAS
		Stearic Acid	57-11-4	3%	0.19%	21 CFR 184.1409 - GRAS
Paraloid K-445	5.07%	Butyl acrylate, methyl methacrylate, butyl methacrylate polymer	25322-99-0	100%	5.07%	21 CFR 177.1010 - Acrylic and modified acrylic plastics, semirigid and rigid
2220 TiO2	3.17%	Titanium Dioxide	13463-67-7	100%	3.17%	21 CFR 178.3297 - Colorants in Polymers
K175 PA	1.58%	Methyl methacrylate-butyl acrylate-styrene copolymer	27136-15-8	100%	1.58%	21 CFR 175.300 - Resinous and Polymeric Coatings
TM181 Stab	1.35%	Bis(2-ethylhexylthioglycolate) dimethyltin	57583-35-4	75%	1.01%	21 CFR 178.2010 - Antioxidant and Stabilizers for Polymers
		Tris(2-ethylhexylthioglycolate) methyl tin	57583-34-3	25%	0.34%	21 CFR 178.2010 - Antioxidant and Stabilizers for Polymers
Loxiol GE2063	1.32%	No Supplier Information			1.32%	21 CFR 175.300 - Resinous and Polymeric Coatings Based on Supplier Statement

Loxiol G60	0.96%	No Supplier Information			0.96%	No FDA Food Contact
10LD CaSt	0.45%	Calcium Stearate	1592-23-0	100%	0.45%	21 CFR 178.2010 - Antioxidant and Stabilizers for Polymers
Drpx68 ESO	0.42%	Epoxidized soybean oil	8013-07-8	100%	0.42%	21 CFR 175.300 - Resinous and Polymeric Coatings
AC392 PE Wax	0.13%	Oxidized Polyethylene	68441-17-8	100%	0.13%	21 CFR 177.1620 - Oxidized Polyethylene

Conclusions and Next Steps

Based on the FDA compliance of the components and raw materials, all substances are FDA compliant with the exception of Loxiol G60. Because the application of this signboard is not designed to come into contact with food, any contact would be considered incidental. Through a risk assessment using very conservative assumptions, the use of Loxiol G60 completed in **Appendix 1** shows that the use of this substance is in compliance with FDA food contact regulations as outlined in 21 CFR 174.5; *General provisions applicable to indirect food additives*, which includes FDA Incidental Food Contact.

Appendix 1 – Loxiol G60 Risk Assessment

Loxiol G60 is a component of the signboard at 0.96%. The signboard weighs a maximum of 40 lbs (18.1 kg). Therefore, there is approximately 173.8 grams of Loxiol G60 in each sign. The average lifespan of these signs is 20 years (7,300 days).

Total amount of Loxiol G60 that may migrate from sign:

$$173.8 \text{ grams} \div 7,300 \text{ days} = 0.0238 \text{ grams/day} = 23.8 \text{ mg/day}$$

If you assume 100% of Loxiol G60 is consumed by a human (average weight of a human is 60 kg), the Estimated Daily Intake over the lifetime of the sign of this substance is: $23.8 \text{ mg/day} \div 60 \text{ kg} = \mathbf{0.4 \text{ mg/kg/day}}$

According to the supplier, the NOAEL for adult rats is 1,000 mg/kg/day. When dividing by a Safety Factor of 1,000, the Acceptable Daily Intake is:

$$\text{Acceptable Daily Intake} = \frac{\text{NOAEL}}{\text{Safety Factor}} = 1,000 \text{ mg/kg/day} \div 1000 = \mathbf{1.0 \text{ mg/kg/day}}$$

Risk of adverse health effects from migration of substances to food is commonly characterized as the Margin of Exposure (MoE): the ratio of the Acceptable Daily Intake (ADI) and the Estimated Daily Intake (EDI):

$$\text{MoE} = \frac{\text{ADI}}{\text{EDI}} = \frac{1.0}{0.4} = \mathbf{2.5}$$

If the Estimated Daily Intake is below the Acceptable (or Tolerable) Daily Intake, i.e. the ratio is greater than 1, the exposure to the substance is considered safe in the US. Therefore, in this very conservative assessment, the addition of Loxiol G60 for this application is safe.