

FOOD CONTACT COATINGS --- A MANUFACTURER'S PERSPECTIVE

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By Madelyn K. Harding

Senior Manager, Corporate Regulatory Affairs

The Sherwin-Williams Company



OVERVIEW

- Requirements
- Chemistry: Selecting Ingredients
 - G. R. A. S.
 - 21 CFR 175.300, 178.3297...
 - TOR
- Performance
- Other Requirements
- Epoxy resins and Bisphenol A
- Questions





Direct Food Contact

Direct Food Contact between food and coatings

FDA calls this "Indirect Food Additive"

Direct food additives, ex. Salt, pepper

Indirect food additives - eg leaching of plasticizer out of plastic bottles



21 CFR 175.300 - Basic Requirements for Coatings as Indirect Food Additives-Page 1

175.300 Resinous and polymeric coatings used as the food-contact surfaces if

(a) Applied as a continuous film, cured by oxidation, cured by polymerization, condensation, and/or cross-linking without oxidation, or prepared from pre-polymerized substances.

(b) Formulated from substances that are GRAS, permitted by regulations in this part, or listed below in (i) thru (xxxvii)

(c) When extracted with solvent(s) characterizing the type of food, and under conditions of time and temperature representative of intended use [see P (d) Tables 1 and 2] yield extractives limited as shown.





21 CFR 175.300 - Basic Requirements-Pg 2

(d) Tables

TABLE 1—TYPES OF FOOD
PROCEDURES

TABLE 2—TEST

(e) *Analytical methods—(1) Selection of extractability conditions.*

(f) *Equipment and reagent requirements*

(g) Finished coatings intended for repeated food-contact use shall be **thoroughly cleansed prior to their first use in contact with food.**

(h) Acrylonitrile copolymers comply with 21 CFR 180.22.



Basic Requirements for Coatings as Indirect Food Additives-In English

- Chemistry must comply with regulatory requirements, and
- Overall leaching performance must be below the requirements

Typically first the formula ingredients are established, then the leaching tests are performed.



CHEMISTRY

Selecting Ingredients



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Generally Recognized As Safe



GRAS -

Generally Recognized as Safe

- GRAS ingredients are found throughout 21 CFR - sections 182, 184, 186
- Different requirements/conditions are placed upon their use in coatings, depending on which section.



GRAS - Generally Recognized as Safe

- **Section 184.1 states,**
“Ingredients affirmed as GRAS in this part are also GRAS as indirect human food ingredients, subject to any limitations prescribed in parts 174, 175, 176, 177, 178 or § 179.45 of this chapter or in part 186 of this chapter. The purity specifications in this part do not apply when the ingredient is used in indirect applications. However, when used in indirect applications, the ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.”
- **Section 182.1 states,**
“The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.
“The substance is of appropriate food grade and is prepared and handled as a food ingredient.”





GRAS - Glycerin as An Example

21 CFR 182.1320

Glycerin.

(a) *Product.* Glycerin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice



Versus Synthetic Glycerin

172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

.... may be safely used in food, subject to the provisions of this section:

- (a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.
- (b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

172.5” may be safely used predicate usage under conditions of good manufacturing practice... as defined to include the following:

- (1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.
- (2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient”



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21 CFR 175.300 (b) (3)

Lists **specific** chemistries which are approved for use in food contact coatings....

Also refers to section 178.3297 for pigments and other additional acceptable ingredients.





Specific Chemicals -Examples

TiO₂ - approved at 21 CFR 178.3297

TiO₂ Slurry - maybe/maybe not

TiO₂ dispersed as colorant - maybe / maybe not

Cobalt 2-ethylhexoate - approved as a drier

Specific ingredient purchased as a mixture [pre-dispersed] may not be -

Generally - Coating manufacturer depends on ingredient manufacturer certification



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Threshold of Regulation



T.O.R.

Threshold of Regulation

**Ingredients NOT in 21 CFR and NOT GRAS -
what now?**

The dilemma of formulating only with materials listed in 21 CFR was solved in recent years.

FDA has acknowledged the ability of companies to use "no migration" to determine that a substance does not become a food additive.





T.O.R - Threshold of Regulation for Substances Used in Food-Contact Articles

FDA exempts substances from regulation as food additives if use meets 21 CFR 170.39

Food additive petition is not required for exempted use



T.O.R. @ 21 CFR 170.39

1. Not carcinogenic, no reason to suspect carcinogenic, no carcinogenic impurities with TD_{50} chronic feeding < 6.25 mg/kg-day,
2. No other health/safety concerns because,
 1. Use shown to result in dietary concentrations ≤ 0.5 ppb [= to dietary exposures ≤ 1.5 micrograms/person/day] OR
 2. Substance is regulated for direct addition into food, AND dietary exposure resulting from proposed use $\leq 1\%$ of acceptable daily intake [ADI]
3. Substance has no effect in or on food, AND
4. Substance use has no adverse impact on environment



No Migration - How determine? Start Simple

Assume all of the ingredient migrates out of coating into food that is in railcar, and determine the highest potential level in the food. Evaluation based on

- Size of rail car
- Amount of coating
- Life of coating
- Re-fill cycle of food into railcar



And if that fails, then....the Not so Simple Procedure

- Perform migration studies of ingredient in question using appropriate food simulating solvents under worse case use conditions [time/temperature]
- FDA has established guidelines for the testing.

[Complicated procedure - not included here]





Leaching Performance

[Not Migration Studies]





Leaching Performance

1. Type of food
2. Conditions of use [temperatures]
3. Extractants
4. Examples



Leaching Performance Types of Food

- I. Nonacid (pH above 5.0), aqueous products;
May contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- II. Acidic (pH 5.0 or below), aqueous products;
May contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
 - A. Water-in-oil emulsion, high- or low-fat.
 - B. Oil-in-water emulsion, high- or low-fat.
- V. Low moisture fats and oils.
- VI. Beverages:
 - A. Containing alcohol
 - B. Nonalcoholic
- VII. Bakery products.
- VIII. Dry solids (**no end test required**)



Leaching Performance Conditions of use

High temperature heat-sterilized eg., over 212 °F).

Boiling water sterilized

Hot filled or pasteurized above 150

Hot filled or pasteurized below 150

Room temperature filled and stored thermal treatment in the container).

Refrigerated storage, no thermal treatment in the container).

Frozen storage (no thermal treatment in the container).

Frozen storage: Ready-prepared foods intended to be reheated in container at time of use:.

1. Aqueous or oil in water emulsion of high or low fat.
2. Aqueous, high or low free oil or fat.



Leaching Performance - Extractants

■ Water	■ Heptane 1,2	■ 8 % alcohol
■ 250 °F, 2 hr	■ 150 °F, 2 hr	■ 150 °F, 2 hr
■ 212 °F, 30 min	■ 120 °F, 30 min	■ 120 °F, 24 hr
■ Fill boiling, cool to 100 °F	■ 120 °F, 15 min	■ 70 °F, 48 hr
■ 150 °F, 2 hr	■ 120 °F, 30 min	
■ 120 °F, 24 hr	■ 70 °F, 30 min	■ <i>Chloroform</i>
■ 70 °F, 48 hr		





Leaching - An Example

Test Procedures to Determine Amount Of Extractives From Coating, Using Solvents Simulating Types Of Foods & Beverages

Use: Boiling water sterilized

Food Type	Water	Heptane
II	(time & temperature)
III, VII	212 °F, 30 min	120 °F, 30 min.



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Leaching Performance - Results

Concentration of Extractive residue must be less than:

50 ppm,

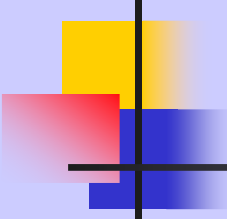
and chloroform-soluble extractives, based on container size and repeated or one time use:

1 gallon container, one time use: 0.5 mg/in²

>1 gallon container, one time use: 1.8 mg/in²

Container for repeated use: 18 mg/in²





Other Requirements

In accordance with good manufacturing practice, finished coatings intended for repeated food-contact use shall be thoroughly cleansed prior to their first use in contact with food.





Epoxy Resins and Bisphenol A

Where does FDA stand?

The Good

The Bad

The Ugly





Bisphenol A: FDA - Aug. 15, 2008

FDA released draft assessment

Includes use in baby bottles

Reaffirms safety of products made
from polycarbonate plastic and epoxy
resins





Bisphenol A: FDA - Aug. 15, 2008

Draft assessment states: "FDA concludes that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults."





Bisphenol A - NTP & NIH

National Toxicology Program (NTP) of the National Institutes of Health published a Draft Brief indicating that some studies in animals suggest that BPA may raise concerns for developmental effects in humans.





Bisphenol A: FDA - Oct. 31, 2008

On October 31, 2008, BPA subcommittee of FDA's Science Board raised questions about whether FDA's review had adequately considered the most recent scientific information available.



Bisphenol A:

Science Board Peer Review to FDA

- **Expand/Update exposure assessment**
- **Consider dose modeling**
- **Clarify uncertainty factors used**
- **Reevaluate toxicity studies deemed “adequate”**
- **Consider the value of meta-analysis**
- **Expand discussion of biomonitoring data**
- **Carefully consider planned tox. studies: ensure they may clarify uncertainties**



Bisphenol A - FDA Science Board Meeting - Feb. 24, 2009

Agreement that

BPA is toxic at some level

BPA leaches at some level



Bisphenol A - FDA Science Board Meeting - Feb. 24, 2009 - Page 2

Health Canada assessment: removed polycarbonate bottles from market [under Chemical Management NOT Food Safety statute]

According to FDA spokesperson, Health Canada "acted out of an abundance of caution."



Bisphenol A - FDA Science Board Meeting Feb. 24, 2009 - Page 3

New Infant Formula Data vs. data used by FDA in Draft Assessment:

Comparable

BPA levels at 0.02 - 10.55 microgram/kg food



Bisphenol A - FDA Science Board Meeting Feb. 24, 2009 - Page 4

Ongoing Activities

1. Concentrate on BPA from polycarbonate bottles and from baby formula
2. Continue toxicology evaluations
3. Collaborate with NIH for Epidemiology studies
4. Collaborate with HealthCanada to meet with industry on voluntary efforts to reduce BPA exposure to infants





Bisphenol A: FDA - June 3, 2009

- FDA Commissioner Dr. Margaret A. Hamburg testified before the House Committee on Energy and Commerce's Subcommittee on Health.
- In response to a question about BPA, Dr. Hamburg emphasized that she takes the questions that have been raised about BPA “**very seriously.**”
- The FDA's new Acting Chief Scientist, Dr. Jesse Goodman, is working with FDA scientists to take a fresh look at the science of BPA.





Bisphenol A - CONCLUSION

A lot of bad press towards FDA

A lot of attention is directed at the safety issues associated with BPA

Restrictions on its presence may be imposed in the future.





QUESTIONS.....



**ASK
SHERWIN-WILLIAMS**

