

# Epoxy Curing Agents Used in Contact with Food or Potable Water



## INTRODUCTION

---

In the coatings industry, there are a number of applications where the coating needs to comply with regulations for safe use regarding contact with food or potable water. Depending upon the specific application, the requirements of the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) or NSF International (NSF) may be applicable.

Epoxy coatings are widely used for applications requiring contact with food or potable water. The regulations regarding the required testing

and the approval process for epoxy coatings under each of these areas are different. The purpose of this bulletin is to:

- provide general information on the FDA, USDA and NSF compliance processes;
- list the Evonik epoxy curing agents and modifiers that can be used in compliance with the current FDA requirements (e.g., 21 CFR 175.105 and 21 CFR 175.300); and
- list the Evonik epoxy curing agents and modifiers for which compositions have been filed with NSF.

### FDA Compliance

There are two main types of epoxy applications in the food industry which may be subject to the FDA regulations as reported in the Code of Federal Regulations (CFR), Title 21 requirements:

- Resinous and polymeric coatings (21 CFR 175.300), and
- Adhesives (21 CFR 175.105).

Because resinous and polymeric coatings are extremely complex materials and are often crosslinked and of no clearly defined chemical composition, Section 175.300 lists materials which may be used in the manufacture of polymeric coatings intended for use in direct contact with food applications. Similarly, Section 175.105 lists substances that

may be used to prepare adhesives.

**Formulators should keep in mind, however, that it is the finished, formulated system that must comply with these FDA regulations, including the end use and extractive limitations.**

An epoxy system that meets the requirements set forth in these regulations is said to be “used in accordance with,” or “used in compliance with CFR Title 21, Part 175.300 or 175.105.” It is not said to be “FDA approved,” because the FDA does not “approve” specific company’s formulated systems. The responsibility of determining a specific epoxy system’s (finished, cured product) compliance is carried out by the system’s manufacturer. The manufacturer should refer to the FDA’s food

additive regulations, which are published in Title 21 of the Code of Federal Regulations. For more information about 21 CFR, please go to: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

For information about the US Government Printing Office, who publishes the CFR, please call 202.512.1800 or go to <https://www.gpo.gov/contact.htm> for contact information.



## Determining FDA Compliance

Manufacturers need to determine whether their formulated epoxy systems for use in coatings or adhesives for food contact articles comply with FDA requirements by evaluating the regulatory status of the raw materials used in their manufacture:

1. 21 CFR Sections 175.105, "Adhesives," and 175.300, "Resinous and polymeric coatings," contain lists of ingredients that are cleared by the FDA for use in the manufacture of adhesives and coatings for food contact articles, respectively. Coating manufacturers must assure that every raw material used in their formulation is included in the applicable list or that it meets any

and all end use and extractive limitations set forth in the regulation.

If the compositions of some raw materials in the formulation are unknown, the coating manufacturer should contact his suppliers for additional information to determine FDA status of those particular components.

2. If any raw material in the formulation is not found on the "compliant ingredient" list for the FDA part in question, the coating manufacturer must assure that an unlisted component does not migrate and become a component of food.

Evonik evaluates whether its products are cleared under FDA requirements and prepares FDA compliance letters which are available to customers for all of its

epoxy curing agents, resins, diluents and modifiers. A list of epoxy-related products for which FDA compliance letters are available is presented in Table 1. For a copy of the letter for a particular product, please call 1-800-345-3148 (outside the U.S. or Canada, 610-481-6799).

The FDA regulations specified in this bulletin were in effect at the time of its compilation, but they are subject to change. No chemical should be used in a product or process in which it might contact a food, drug or cosmetic until you have determined the safety and legality of its use.

**Coating manufacturers should seek professional/legal assistance to clarify any questions regarding the FDA compliance of their formulations.**

## USDA Compliance

Some in the industry may recall the Food Safety and Inspection Service (FSIS) Directive 11,000.4, "Approval of Paints and Coatings Used in Official Establishments." FSIS made approvals under this directive generally by consulting with the FDA regarding the status of the substance or compound as an FDA-approved direct or indirect food additive. Thus, the FSIS approval was somewhat redundant.

In 1997, the USDA published a Federal Register informing the industry that FSIS would no longer be approving requirements for equipment. No issuance has replaced 11,000.4, therefore the FSIS no longer makes approvals for materials such as chemicals, compounds, sanitizers, and coatings.

Consequently, establishments, not FSIS will be responsible for determining whether nonfood compounds and proprietary substance are safe and effective.

For more information about the Federal Register, please use the following link:

<https://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-007N.htm>

## NSF International Standards Approval

The primary function of NSF is to operate as a neutral medium through which industry, regulatory agencies and the public address health and environmental issues involving products, equipment, procedures and services. As a part of this effort, the NSF participates in the development of industry-wide standards for equipment, products and services that impact potable water delivery systems, e.g., water pipes and storage tanks.

Manufacturers of epoxy coatings that require NSF approval will be concerned primarily with ANSI/NSF Standard 61, "Drinking Water System Components—Health Effects." This standard addresses two aspects of drinking water system components:

- contaminants which may enter the drinking water from the epoxy coating, and
- the acceptable levels of those contaminants from a public health point of view.

The first step in obtaining ANSI/NSF Std 61 approval is to contact the NSF. Please see the NSF website at:

<http://www.nsf.org/contact-us/>

or contact the NSF at:

**1.800.NSF.MARK**

**1.800.673.6275**

**info@NSF.com**

Once you have reached the correct regional contact, the contact will send the appropriate application packets. The process then continues as follows:

- The caller will receive an application packet from the NSF containing forms to be completed, including a Product/Materials Information Form (P/MI) and a Toxicology Data Review Submission Form (TDRS-A).

**TABLE 1**

Following is an updated list of our epoxy curing agents and diluents with letters indicating current FDA compliance status.

Product Name	REGULATION NUMBER		
	21CFR 175.105	21CFR 175.125	21CFR 175.300
AMICURE® CG 1200G curing agent	+++		+++
AMICURE® CG1200	+++		+++
AMICURE® CG1400	+++		+++
AMICURE® CG325	+++		+++
AMICURE® CGNA	+++		+++
AMICURE® PACM	++		
ANCAMIDE® 220 curing agent	+++		+++
ANCAMIDE® 220-IPA-73	+++		+
ANCAMIDE® 220-X-70	+++		+
ANCAMIDE® 2426			++
ANCAMIDE® 2447	+++		+++
ANCAMIDE® 260A	++		+++
ANCAMIDE® 261A	+++		
ANCAMIDE® 350A	++		+++
ANCAMIDE® 375A	++		+++
ANCAMIDE® 500	+++		+++
ANCAMIDE® 502	+++		+++
ANCAMIDE® 503	+++		+++
ANCAMIDE® 506	+++		+++
ANCAMIDE® 507	++		+++
ANCAMIDE® 700-B-75	+++		
ANCAMIDE® 702-B-75	+++		
ANCAMIDE® 903MAV	+++		+++
ANCAMIDE® 910	++		
ANCAMINE® 1608	++		+++
ANCAMINE® 1618	+++	+++	++
ANCAMINE® 1638	++		+++
ANCAMINE® 1693	++		
ANCAMINE® 1916	+++		+++

Product Name	REGULATION NUMBER				
	21CFR 175.105	21CFR 175.125	21CFR 175.300	21CFR 176.180	21CFR 177.1650
ANCAMINE® 1922A	+++				
ANCAMINE® 2089M	+++				
ANCAMINE® 2264	++				
ANCAMINE® 2280	++				
ANCAMINE® 2410	+++		+++		
ANCAMINE® 2410B75	+++		+		
ANCAMINE® 2422	+++				
ANCAMINE® 2432	+++				
ANCAMINE® 2623	+++	+++	++		
ANCAMINE® 2719	++				
ANCAMINE® DETA	+++		+++		
ANCAMINE® K54 <sup>1</sup>	+++		++		
ANCAMINE® K61B <sup>1</sup>	+++		++		
ANCAMINE® T	+++				
ANCAMINE® TEPA	+++		+++		
ANCAMINE® TETA	+++		+++		
ANCAREZ® 2364 resin modifier	+++				
ANCATHERM® 502 resin	+++				
DICYANEX™ 1200 curing agent	+++		+++		
DICYANEX™ 1400B	+++		+++		
DICYANEX™ 325	+++		+++		
EPODIL® 741 diluent	++				
EPODIL® 748 <sup>2</sup>	++		++	++	++
EPODIL® 749	++				
EPODIL® 750	++				
EPODIL® LV5	+++				
HYBRIDUR® 580 dispersion	+++				
HYBRIDUR® 870	+++				
HYBRIDUR® 878	+++				

+++ compliant ++ compliant with restrictions + see letter for restriction details



**TABLE 2**

Epoxy Additives with "Optional Authorization" TDRS-B Forms for NSF (as of 6/17/2014)

AMICURE® 101	ANCAMINE 1769
AMICURE CG-NA	ANCAMINE 1784
AMICURE CG-1200	ANCAMINE 1856
AMICURE PACM	ANCAMINE 1884
ANCAMIDE® 220-X-70	ANCAMINE 1895
ANCAMIDE 260A	ANCAMINE 1916
ANCAMIDE 350A	ANCAMINE 2014 AS
ANCAMIDE 2050	ANCAMINE 2021
ANCAMIDE 2353	ANCAMINE 2072
ANCAMIDE 2396	ANCAMINE 2074
ANCAMIDE 2443	ANCAMINE 2089M
ANCAMIDE 500	ANCAMINE 2143
ANCAMIDE 501	ANCAMINE 2167
ANCAMIDE 502	ANCAMINE 2205
ANCAMIDE 506	ANCAMINE 2264
ANCAMIDE 700 B-75	ANCAMINE 2280
ANCAMIDE 805	ANCAMINE 2422
ANCAMIDE 2137	ANCAMINE 2432
ANCAMIDE 2386	ANCAMINE 2489
ANCAMIDE 3031	ANCAMINE 2505
EPODIL® 748	ANCAMINE 2579
EPODIL 749	ANCAMINE 2715
EPODIL 757	ANCAMINE DL-50
ANCAMINE® 1608	ANCAMINE K54
ANCAMINE 1618	ANCAMINE MCA
ANCAMINE 1637	ANCAMINE TETA
ANCAMINE 1638	ANCHOR® 1040 curing agent
ANCAMINE 1644	CUREZOL® C17Z curing agent
ANCAMINE 1693	IMICURE® EMI-24 curing agent
ANCAMINE 1767	ANCAMINE® curing agent

All forms should be completed and returned to NSF.

- An NSF toxicologist will examine the completed forms and determine if more information is needed about the individual components of the manufacturer's formulation.

If so, a TDRS-B Form will be forwarded to the manufacturer, who in turn should forward it to the supplier of the raw material in question. For Evonik's epoxy curing agents, resins, diluents and modifiers, forms should be submitted to: [proinfo@evonik.com](mailto:proinfo@evonik.com)

NOTE: Once a TDRS-B Form has been completed on a product, the supplier has the option of providing NSF with "Optional Authorization" rights, which allow NSF to use the TDRS-B Forms for the review/acceptance of other products containing the material in question. A list of Evonik's epoxy curing agents, resins, diluents and modifiers for which NSF has been granted "Optional Authorization" by Evonik is presented in Table 2. Formulations and all paperwork must still be submitted for each new epoxy formulation, but the "Optional Authorization" status expedites NSF

approval process since completed TDRS-B Forms are already on file with NSF.

- Once all TDRS Forms have been completed, NSF chemists and toxicologists will review the manufacturer's formulation and select which analytical tests must be run in order to determine if the system meets Standard 61 criteria. NSF will then work with the manufacturer to obtain samples of their formulation to test in NSF laboratories.

Previously completed toxicology studies may also be used to evaluate the formulation.

After all auditing has been completed, NSF will notify the manufacturer of the formulation's status regarding Standard 61. If it is approved, they will send the manufacturer an "Authorized Registered Formulation" and a listing package which allows the manufacturer to be listed in NSF's annual listing book.

NOTE: The manufacturer automatically receives a copy of the annual NSF listing book if their formulation is approved.

The presence of benzyl alcohol in epoxy curing agents can affect the FDA status of an epoxy formulation for coatings applications.

Evonik has developed a model to account for many of the common variables associated with use of curing agents in coatings applications and their impact on FDA status suitability. Using this model as a guide may increase the selection of products for FDA-compliant applications to include Ancamide 2050 and Ancamine 1618 curing agents. Contact your local sales representative or call 800-345-3148 for further information on this capability.

Footnotes:

(1) Curing agents are subject to the provisions of paragraphs (c) (3) or (4) of 21 CFR 175.300, which include extractive limitations for coatings in contact with food. The coating manufacturers are responsible for determining if the coatings meet these limitations.

(2) Compliance with 21 CFR 175.300, 21 CFR 176.180 and 21 CFR 177.1650 is limited to the use of Epodil 748 diluent in coatings intended to contact dry bulk foods at room temperature. \*Evonik regularly reviews the FDA compliance status of its curing agents and diluents. Call 1-800-345-3148 for the most current information on FDA compliance status.

**PLEASE NOTE THAT THE COATING MANUFACTURER IS RESPONSIBLE FOR DETERMINING THAT THE SOLVENT IS REMOVED FROM THE COATING DURING THE CURING PROCESS. ADDITIONALLY, THE LISTED CLEARANCES ARE SUBJECT TO SPECIFIC END-USE AND EXTRACTIVE LIMITATIONS CITED IN THE REGULATIONS. MEETING THESE CLEARANCES IS THE RESPONSIBILITY OF THE COATING MANUFACTURER.**

**EVONIK CORPORATION**

7201 Hamilton Blvd.  
Allentown, PA 18195  
1 800 345-3148  
Outside U.S. and Canada 1 610 481-6799

**For Technical Information and Support:**

Americas: [prodinfo@evonik.com](mailto:prodinfo@evonik.com)  
EMEA: [apcse@evonik.com](mailto:apcse@evonik.com)

**For Samples:**

Americas: [prodinfo@evonik.com](mailto:prodinfo@evonik.com)  
Asia: [picasia@evonik.com](mailto:picasia@evonik.com)  
EMEA: [apcse@evonik.com](mailto:apcse@evonik.com)

**For Customer Service:**

US / Canada  
[cspolyur@evonik.com](mailto:cspolyur@evonik.com)

LASA  
[lachem@evonik.com](mailto:lachem@evonik.com)

Japan  
[pmdcsojp@evonik.com](mailto:pmdcsojp@evonik.com)

Asia  
PMD-Asia Customer Service:  
[pmdcso@evonik.com](mailto:pmdcso@evonik.com)  
APCS PMGP (Korea):  
[apckr@evonik.com](mailto:apckr@evonik.com)

EMEA:  
[apcsep@evonik.com](mailto:apcsep@evonik.com)

The information contained herein is offered without charge for use by technically qualified personnel at their discretion and risk. All statements, technical information and recommendations contained herein are based on tests and data which we believe to be reliable, but the accuracy or completeness thereof is not guaranteed and no warranty of any kind is made with respect thereto.

