PEI/Cr V /0041

جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی

وزارت بهداشت، درمان وآموزش پزشکی

معاونت غذا و دارو

اداره کل نظارت بر مواد غذایی، آشامیدنی، آرایشی و بهداشتی

حداقل ضوابط فنی و بهداشتی واحدهای تولید کننده مواد شیمیایی مصرفی (پوششها و درزگیرها) جهت بسته بندیهای فلزی پایه فولادی برای مواد غذایی

تدوین: اردیبهشت ۱۳۸۹

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بنام خدا

پیشگفتار :

روند رو به رشد تعداد واحدهای تولیدی صنایع غذایی و آشامیدنی و ایجاد تغییرات در تکنولوژی و تنوع و گوناگونی محصولات تولیدی ، سبب گردید تا اداره کل نظارت بر مواد غذایی، آشامیدنی ، آرایشی و بهداشتی از سال ۱۳۸۱ اقدام به تدوین مقررات و ضوابط جدید متناسب با علم روز غذا نماید. تدوین ضوابط مذکور شامل حداقل ضوابط تاسیس و بهره برداری کارخانجات مختلف غذایی تا سال ۱۳۸٤ ادامه یافت ولیکن از تیر ماه سال ۱۳۸۵ سیاست تدوین ضوابط تغییر و مقرر گردید ضوابط فنی و بهداشتی برای تاسیس و بهره برداری واحدهای تولید و بسته بندی مواد غذایی بصورت ضابطه ای کلی تدوین گردد و سایر موارد از جمله تجهیزات خط تولید، آزمایشگاه و ضوابط بهداشتی اختصاصی برای تولید هر محصول درضوابط جداگانه ای مختص به هر محصول تدوین و به تصویب برسد.

برای هماهنگی با توسعه جهانی، ضوابط در مواقع لزوم اصلاح خواهد شد بدین منظور پیشنهادات مطروحه توسط کمیته علمی مورد بررسی قرار گرفته و پس از تایید ، ضابطه اصلاح شده از طریق واحد اطلاع رسانی به اطلاع عموم خواهد رسید.

شایان ذکراست که ضوابط بر روی سایت معاونت غذا و دارو وزارت بهداشت (www.fdo.ir) موجود می باشد.

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این ضابطه توسط اداره کل نظارت بر مواد غذایی، آشامیدنی، آرایشی و بهداشتی وبا همکاری :

اداره کل آزمایشگاه های کنترل غذا و دارو، مؤسسه استاندارد و تحقیقات صنعتی ایران، شرکت ماندانا شیمی، شرکت سپند رنگ و شرکت گوهرفام تدوین گردیده است.

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فهرست مطالب

لازم به ذکر است، موارد مندرج در کادر طوسی رنگ بعنوان توصیه می باشند.

۱- مقدمه

بسته بندی به محافظی اطلاق می گردد که بتواند سلامت کالای محتوی خود را پس از تولید تا زمان مصرف حفظ نماید. از طرفی بسته بندی علاوه بر این حفاظت، وظیفه دیگری نیز بر عهده دارد و آن شناساندن کالا به خریدار است. بسته بندی مانند پل ارتباطی میان خریدار و کالاست . صنایع بسته بندی وظیفه بزرگی را در ماندگاری، حفاظت ، نگهداری ، سهولت و دوام در حمل و نقل کلیه محصولات غذایی و کشاورزی بعهده دارد. ضمن اینکه بسته بندی مناسب و شکیل در بازاریابی و ایجاد رضایت مشتری نقش بسزایی را ایفا می نماید که این موضوع هم در بازار داخلی و هم در امر صادرات از اهمیت ویژه ای برخوردار می باشد.در حال حاضر صنایع متعدد و مختلفی در امر بسته بندی فعالیت می نمایند و هر کالایی با توجه به ماهیت فیزیکو شیمیایی و بهداشتی خود از یکی از انواع بسته بندی استفاده می نماید. با توجه به پیشرفت تکنولوژی و دستیابی به دانش فنی ، در حال حاضر صنایع بسته بندی فلزی می توانند بعنوان یکی از اقتصادی ترین روشهای بسته بندی در کشور مورد استفاده قرار گیرند.

۲- هدف

هدف از تدوین این ضابطه تعیین حداقل ضوابط فنی و بهداشتی واحدهای تولید کننده مواد شیمیایی مصرفی (پوشش ها و درزگیرها) جهت بسته بندی های فلزی پایه فولادی برای مواد غذایی می باشد.

۳- دامنه کاربرد

این ضابطه در مورد واحدهای تولید کننده مواد شیمیایی مصرفی (پوششها و درزگیرها) جهت بسته بندیهای فلزی پایه فولادی برای مواد غذایی کاربرد داردوجهت تاسیس واحد، حداقل ضوابط فنی و بهداشتی ذکر شده در GMP عمومی نیز باید مد نظر قرار گیرد.

تعاریف و اصطلاحات

– پوشش های داخل بسته بندی فلزی

آمیزه ای شیمیایی همگن از پلیمرهای مختلف و افزودنی ها از قبیل : حلال ها، رنگدانه ها، پر کننده ها، روان کننده ها، پایدار کننده ها، بازدارنده ها، نرم کننده ها، کاتالیزورها و دیگر ترکیبات مورد نیاز است که به منظور حفاظت ورق فلزی و یا بسته بندی فلزی از خوردگی بر روی سطوح داخلی تحت شرایط دما و زمان مشخص نشانده می شود.

یادآوری

معمولاً پوشش ها با عناوین زیر نام برده می شوند ورنی [۱]، سایز [۲]، لعاب [۳]، لاک [٤]، پوشش پودری [٥]، پوشش [٦] و مانند آنها.

– پوشش پودری

به پوشش همگنی از انواع رزین، رنگدانه و سایر مواد افزودنی که به صورت ذرات جامد بسیار کوچک توسط روش الکترواستاتیک بر روی ورق فلزی یا بسته بندی فلزی اعمال می گردد، گفته می شود.

– پوشش های گرما سخت [۷]

به پوشش هایی که پلیمرهای موجود در آن بر اثر عواملی مانند حرارت با افزایش وزن مولکولی همراه بوده و واکنش های انجام شده برگشت ناپذیر می باشند، پوشش های گرما سخت گویند.

– پوشش سیال

مخلوط همگنی از انواع رزین، رنگدانه، حلال (آلی و یا آبی) و سایر مواد افزودنی در فاز مایع می باشد که توسط سیلندرهای غلطکی یا اسپری یا روش های معمول دیگر بر روی ورق فلزی یا بسته بندی فلزی نشانده می شود.

1-Varnish
2-Size
3-Enamel
4-Lacquer
5-Powder coating
6-Coating
7- Thermoset

- بسته بندی فلزی

به قوطی فلزی، انواع سر و کف قوطی، درپوش فلزی [1] ، تیوپ آلومینیومی، درپوش پیچی فلزی [2]، درپوش آلومینیومی [3]، درپوش آلومینیومی با حلقه نگهدارنده [4]، ظروف فلزی [5]، درپوش آسان بازشو [6]، تشتک فلزی [7]، قوطی آئروسل [8] و مانند آنها گفته می شود.

• مواد افزودنی [1]

مواد افزودنی در پوشش ها موادی هستند که باعث تسریع فعل و انفعالات، انتشار، توزیع مواد متشکله، افزایش خاصیت همترازی و ایجاد حالت لغزندگی در پوشش و بهبود خواص مکانیکی آن می شود. مواد افزودنی شامل :

• حلال [9]

حلال بستر حل کننده و حمل کننده رزین و رنگدانه موجود در پوشش ها می باشد و یکنواختی لازم را پس از انجام پخت رزین ها و تشکیل فیلم موردنظر بر سطح بسته بندی فلزی ایجاد می کند. حلال ها شامل بوتیل گلیکول ،اتیل گلیکول و مانند آنها می باشند.

• رزین [10]

بخش عمده ای از پوشش های مورد مصرف جهت بسته بندی فلزی را رزین های طبیعی و مصنوعی تشکیل می دهند.

انواع رزین طبیعی و مصنوعی عبارتند از وینیل ها، اپوکسی فنل ها، اپوکسی ها، پلی استرها و مانند آنها که در ساخت پوشش ها مورد استفاده قرار می گیرند.

• رقیق کننده [11]

مخلوطی از حلال های مختلف می باشد که جهت کاهش گرانروی پوشش سیال بکار می رود.

• رنگدانه(پیگمان) [12]

رنگدانه ها ذرات پودری شکل و رنگی هستند که به منظور تأمین رنگ و پوشانندگی مناسب به آمیزه پوشش اضافه می شوند. رنگدانه ها از قبیل دی اکسید تیتانیم ، اکسید روی، آلومینیوم و مانند آنها می باشند.

1- Twist – off cap
2- Screw cap
3- Aluminium cap
4- Pilfer proof
5- Drum
6- Easy open
7- Crown closures
8- Aerosol Can
9- Solvent
10- Resin
11- Thinner
12- Pigment

- پوششهای خارج بسته بندی فلزی (بدون تماس با مواد غذایی)

- پوشش های خارج بسته بندی فلزی به معنای هر نوع مخلوط تولید شده از رنگ، اتصال دهنده[۵]، نرم کننده[۶] ، حلال، خشک کن و سایر افزودنی هاست. فرمول این پوشش ها بر پایه حلال، بر پایه آب ، اولئورزینی با روش پخت به وسیله منابع انرژی[۷] مانند اشعه ماوراء بنفش یا الکترونی می باشد. این پوشش ها می توانند به روش های مختلف چاپ یا ورنی زنی مانند فلکسوگرافی [۸]، گراور [۹] ، لترپرس[۱۰] ، افست[۱۱] ، چاپ اسکرین[۱۲] و پوشش با غلطک[۱۳] به کار روند.

- پوشش های خارج بسته بندی فلزی در نهایت به شکل فیلم های نازکی از جوهر چاپ یا ورنی خشک شده یا سخت شده روی سطح بسته بندی که در تماس با ماده غذایی می باشند، در می آیند.

1-Additives
2- Based coat
3- Printing inks
4- Varnish
5- Binder
6- Plasticiser
7- Energy- curing
8- Flexography
9- Gravure
10- Letter press
11- Offset
12- Screen printing
13- Roller coating

- درزگیرها

• درزگیرهای آشکار

این گروه بعنوان واشر آب بندی در داخل محصولاتی چون تشتک ، درب جار و ..... بکار می روند و بسته به مصرف نهایی افزودنیهای متفاوتی در آنها استفاده می شود. درزگیرهای آشکار می توانند بصورت پوششی فوم دار و یا بدون فوم تولید گردند واجزای تشکیل دهنده آنها می بایست با استناد به 21 CFR177.1210 انتخاب شوند.

این درزگیرها که در تماس مستقیم با ماده غذایی قرار می گیرند، باید علاوه بر حفظ چسبندگی به سطح درب ، بتوانند در دامنه گسترده ای از محیط ماده غذایی مقاومت نمایند.

• درزگیرهای نهان

منظور از اعمال درزگیرهای نهان جهت مصارف غذایی در سر و کف بسته بندی فلزی ، ممانعت از خروج مواد مایع و آبکی داخل ظرف به بیرون (بعلت وجود منافذ و درزها) و همچنین جلوگیری از تهاجم عوامل غیر مجاز از خارج به داخل ظرف می باشد. درزگیرهایی که عموما" دارای پایه آبی می باشد ، در سرو کف های معمولی و آسان باز شو بکار می روند. انتخاب ماده اولیه سازنده این گروه حتما" باید با رعایت دستورالعمل 21CFR177.1210 صورت پذیرد. استفاده از سایر درز گیرهای پایه حلالی و یا حتی پلاستی سولها با مصرف بصورت نهان ،ضمن رعایت قانون فوق بلامانع است.

۴- GMP

جهت تاسیس واحد، GMP عمومی و اختصاصی باید مد نظر قرار گیرد.

۴-۱- GMP عمومی

GMP عمومی شامل حداقل ضوابط فنی و بهداشتی واحدهای تولیدکننده مواد بسته بندی غذایی،آشامیدنی، آرایشی و بهداشتی (فیلم ها، مقوا، بطری، لاک ها، پوشش ها و .....) می باشد،که با کد PEI/CrV/0034 برروی سایت معاونت غذا و دارو وزارت بهداشت(www.fdo.ir) موجود می باشد.

یادآوری

تولید کننده پوشش موظف است که با اطلاع از معیارهای ملی مصوب ، ضوابط جاری وزارت بهداشت، درمان و آموزش پزشکی، قوانین جهانی و انتخاب مناسب مواد تشکیل دهنده از مهاجرت غیر مجاز مواد جلوگیری نماید.

۴-۲- GMP اختصاصی

۴-۲-۱- انبار

۴-۲-۱-۱- انبار روبسته مواد اولیه شیمیایی

این انبار باید مجهز به وسایل سنجش دما ورطوبت در نقاط مختلف باشد و در کلیه فصول سال نباید از شرایط دما و رطوبت اتاق خارج گردد ، لذا ثبت روزانه دما و بر اساس دستورالعمل و روش های اجرایی کارخانه ضروری است.

سایر شرایط این انبار باید مطابق با بند ٦-١ حداقل ضوابط فنی و بهداشتی برای تاسیس و بهره برداری واحدهای تولیدکننده مواد بسته بندی، غذایی، آشامیدنی، آرایشی و بهداشتی (فیلم ها، مقوا، بطری، لاک ها، پوشش ها و .....) که با کد PEI/CrV/0034 بر روی سایت معاونت غذا و دارو به نشانی www.fdo.ir قرار دارد ، مطابقت داشته باشد.

۴-۲-۱-۲- انبار روباز مواد شیمیایی

منظور از این انبار، انباری است که بسته بندیهای غیر قابل نفوذ و فاقد آسیب پذیری محیطی مانند تانکرهای حاوی بعضی از حلالها را می توان در آن نگهداری نمود.

فقط موادی می توانند در انبارش باز قرار گیرند که این موضوع بصورت کتبی در برگه اطلاعات ایمنی ماده (MSDS)[1] توسط تولید کننده ماده اولیه تصریح شده و به تائید مسئول فنی رسیده باشد . این مستندات باید در واحد تولیدی در هر زمان در دسترس باشد .

۴ -۲-۱-۳- تانکرهای زیر زمینی

تانکرهای زیر زمینی که جهت نگهداری برخی از مواد اولیه مانند حلالها و روغنها استفاده می شوند، از دستورالعمل انبار روباز تبعیت می نمایند.

۵- ترکیبات مجاز در تولید پوششها و درزگیرها

مواد اولیه شیمیایی مجاز که در ساخت پوششها و درزگیرهای در تماس با ماده غذایی به کار میروند، باید مطابق با رفرانس های ذیل بوده و جزء ترکیبات CMR[2] دسته ۱ و ۲ نباشند.

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[1]-MSDS=Material Safety Data Sheet

2- CMR= Carcinogens, mutagens or toxic to reproduction

- **مواد کمک کننده به پلیمریزاسیون :**

Resolution ap (92) 2 on control of aids to polymerisation (technical coadjuvants) for plastic materials and atricles intended to come into contact with foodstuffs or substances of relevant national regulation

- **پوشش های داخل** : 21CFR175.300 و

Council of Europe:Coatings intended to come into contact with foodstuffs

- **پوشش های خارج** :

Council of Europe:Packaging inks applied to the non- food contact surface of food packaging

- **درزگیرها**: 21CFR 177.1210

- **ترکیبات** CMR:

Consolidated List of C/M/R- Substances- Relating to Points 29,30 and 31 of Annex I of Directive 76/769/EEC

یادآوری

- در مورد فراورده های با خاصیت اسیدیته بـالا ماننـد رب گوجـه فرنگـی ، در صـورتیکه از یکنـواختی پوشش اطمینان حاصل نگردد، باید ترجیحا" پوششها را بصورت دوبار اعمال مورد استفاده قرار داد .

- برای سبزیجات با سولفور بالا مانند ذرت شیرین ترجیحاً از پوشش های با پایه اپوکسی انیدرید استفاده می گردد.

- لاکهای با پیگمنت آلومینیوم و لاکهای با پیگمنت آلومینیوم و اکسید روی(که گاهی نیز دارای واکسهای جدا کننده گوشت از بدنه قوطی می باشند) ، برای مواد آزاد کننده سولفور مانند گوشت ، ماهی و برخی سبزیجات مانند کلم به کار میروند . در صورتیکه pH ماده غذایی از نوع اسیدی باشد، استفاده از اکسید روی مجاز نخواهد بود و لاک دارای آلومینیوم باید بتواند در مقابل کلیه آزمونهای مرتبط در استاندارد ملی ایران به شماره ۲۵۰۹ جواب قابل قبول را کسب نماید .

- لاکهای داخل در جار و تشتک نوشابه میتوانند بصورت تک پوششه از یک لاک تامین کننده چسبندگی به درزگیر (در مواردی که فرآیند حرارتی وجود ندارد) و یا دو پوششه از مجموع یک لاک مقاوم فرآیندی و یک لاک تامین کننده چسبندگی به درزگیر (در شرایطی که عملیات تکمیلی غذا وجود دارد) تهیه گردد.

۶- ویژگی های پوشش های مصرفی

۶-۱- ویژگی های پوشش داخل

پوشش های در تماس با موادغذایی باید دارای شرایط زیر باشند:

۶-۱-۱- اجزاء آنها نباید در مقادیری به ماده غذایی انتقال یابند که باعث به خطر انداختن سلامت انسان شده یا تغییر غیرقابل قبول در ترکیب موادغذایی ایجاد کند و یا خواص ارگانولپتیکی ماده غذایی را تغییر دهد.

۶-۱-۲- این پوشش ها نباید مواد متشکله خود را در مقادیری بیشتر از $10\ mg/dm^2$ بر مبنای سطح کل ماده یا جزء مورد بررسی ، به مواد غذایی منتقل نمایند (مهاجرت کلی [1]) . این حد در موارد ذیل به ۶۰mg از مواد متشکله در کیلوگرم ماده غذایی تغییر می یابد:

- مخازن و یا ظروف پر شونده که دارای ظرفیت کمتر از ۵۰۰ml و بیشتر از ۱۰lit نباشند.
- ظروف پر شونده که سطح در تماس با مواد غذایی آنها قابل اندازه گیری نمی باشند.
- درپوشها ، واشرها ، سربطری ها و سایر موارد مصرفی به منظور آب بندی مورد استفاده قرار می گیرند.

۶-۱-۳- این پوشش ها پس از پخت نباید اجزای مهاجرت کننده ای با وزن مولکولی کمتر از ۱۰۰۰ دالتون را که در رفرانس ذکر شده برای پوشش های داخل (بند ۵) نیامده اند، به مقادیری که برای سلامتی انسان مضر است، به ماده غذایی منتقل نمایند. این موارد ذکر نشده که دارای وزن مولکولی کمتر از ۱۰۰۰ دالتون هستند، باید تحت ارزیابی بحرانی مناسبی قرار گیرند و با توجه به ارزیابی فوق، فعالیت ساختارسمی آنها و میزان حضور آنها در رژیم غذایی مشخص گردد.

1- Overall migration

۶-۲- ویژگی های پوشش خارج

ماده یا کالای چاپ شده نهایی مورد نظر برای بسته بندی های در تماس با مواد غذایی باید الزامات زیر را داشته باشد:

- لایه لاک خورده چاپ شده یا ورنی خورده نهایی نباید در تماس مستقیم با غذا باشد.
- مهاجرت کلی و خاص از ماده یا کالای چاپ شده نهایی نباید از حدود متداول تجاوز نماید.
- پشت پس دهی[1] یا مهاجرت از لایه چاپ شده یا ورنی خورده به سطح در تماس با ماده غذایی، باید صفر یا قابل صرف نظر باشد.

۷- تجهیزات خط تولید

محصول تولید شده مطابق با تکنولوژیهای روز دنیا، باید بتواند همواره کلیه خصوصیات محصول نهایی ذکرشده در استانداردهای معتبر و یا ضوابط اعلام شده از سوی این اداره کل را تامین نماید. تولید مواد شیمیایی باید در محل ها و سالن های مناسب با شرایط کنترل تخلیه مناسب هوای داخل و امکانات اطفا حریق انجام گردد و در آن چشم شور و دوشهای سیفونی نیز پیش بینی شده باشد . سایر مشخصات این خط از دستورالعمل GMPعمومی تبعیت می نماید.

۷-۱- حداقل تجهیزات مورد نیاز برای تولید مواد شیمیایی مصرفی (پوششهای مایع ، پودری ، پودر درزجوش ودرزگیر) جهت بسته بندیهای فلزی پایه فولادی برای مواد غذایی

- مخازن و پاتیلها
- ابزار های توزین (باسکول و ترازو)
- مخلوط کن یا راکتور حل رزین مجهز به همزن
- مخلوط کن تولید محصول مجهز به همزن
- آسیاب (در صورت تولید پوششهای پیگمان دار)
- خشک کن (در صورت تولید پوشش پودری)
- بالابرها
- لوله های انتقال
- پمپ های انتقال
- سیستم پرکن وبسته بندی

1- Set- Off

یادآوری

جنس کلیه تجهیزات باید از نوع مقاوم به خوردگی و Food Grade بوده و با مواد شیمیایی در تماس با آن هیچگونه واکنشی ندهد.

۸- مقررات ایمنی در مهاجرت از مواد شیمیایی مصرفی در تماس با مواد غذایی

- مشتقات اپوکسی، بالاخص بیس فنل A دی گلیسیدیل اتر (BADGE)[1] و محصولات هیدرولیز شدهٔ آن و نیز افزودنیهای هیدروکلرین، باید با توجه به جنبه مسمومیت آنها طبق دستورالعمل مهاجرت خاص مورد بررسی قرار گیرند. (روش اندازه گیری مهاجرت عمومی مطابق استانداردهای 21CFR177.1210 و 21CFR175.300 ضمیمه می باشد و اندازه گیری مهاجرت خاص متعاقباً اعلام خواهد شد).

- مهاجرت BADGE و مشتقات BADGE.H2O و BADGE.2H2O به غذا نباید از حد ۹ mg/kg تجاوز نماید.

- مهاجرت BADGE.HCl.H2O ، BADGE.HCl و BADGE.2HCl به غذا نباید از حد 1mg/kgتجاوز نماید.

- مصرف و وجود بیس فنل F دی گلیسیدیل اتر (BFDGE)[2] در تولید محصولات در تماس با مواد غذایی ممنوع می باشد.

- مصرف و یا وجود نوولاک گلیسیدیل اتر (NOGE) [3]در تولید کلیه محصولات ممنوع می باشد.

- در مورد موادی که هم بعنوان افزودنی در مواد غذایی استفاده می شوند و هم از اجزای اصلی تشکیل دهنده پوشش می باشند (استفاده دوگانه دارند) علاوه بر مشخص نمودن محل مصرف ، مهاجرت بالاتر ازمیزان ۱۰ µg/ ٦ dm^2 نیز باید مورد بررسی قرار گیرد و صرف اطلاق قابلیت مصرف ماده درداخل خوراک و مجاز بودن خوردن آن ، قابل استناد نمی باشد.

1. Bisphenol A diglycidyl ether
2. Bisphenol F diglycidyl ether
3. Novolac glycidyl ether

۹- آزمایشگاهها

کلیه آزمایشات باید مطابق با آخرین تجدید نظر استانداردها و معیارهای ملی و ضوابط جاری وزارت بهداشت، درمان و آموزش پزشکی باشد.

۹-۱- حداقل آزمایشات فیزیکوشیمیایی مورد نیاز

- چگالی (وزن مخصوص)
- گرانروی (برای پوشش های سیال)
- درصد مواد جامد (برای پوشش های سیال)
- نقطه اشتعال (برای پوشش های سیال و حلال ها)
- دانه بندی
- ضخامت پوشش یا وزن فیلم خشک
- چسبندگی فیلم خشک به روش چهارخانه ای
- چسبندگی فیلم خشک در محل لبه برش
- نوچی فیلم خشک
- ضربه (گوی در حال سقوط)
- پایداری فیلم خشک در برابر گوه ای شدن
- جامی شدن گرد یا فنجانی شدن گرد
- مقاومت در برابر خراش (سختی پوشش)
- کنگره ای نمودن فیلم خشک
- پایداری فیلم خشک در عملیات کشش نیمه عمیق و عمیق
- مقاومت در برابر عملیات ساخت بدنه، سر و کف
- مقاومت فیلم خشک در برابر حلال استون
- تعیین نقاط بدون پوشش
- تعیین خلل و فرج
- مقاومت پوشش داخلی بسته بندی فلزی پر شده در برابر مواد غذایی و آشامیدنی
- تعیین نوع رزین فیلم خشک بر روی ورق پوشش داده شده
- آزمون مهاجرت کلی
- آزمون مهاجرت خاص

۹-۲- حداقل لوازم ، تجهیزات مورد نیازدر آزمایشگاه شیمی

- وسایل معمول و ظروف شیشه ای آزمایشگاهی
- ترازو با دقت ۰/۰۰۰۱ گرم
- فویل آلومینیوم
- گرمخانه با جریان هوا
- دسیکاتور معمولی
- دسیکاتور خلاء با درپوش دو سوراخه
- دستگاه اندازه گیری نقطه اشتعال
- الک مخصوص با سوراخ های معین (برای پوشش های پودری)
- دستگاه ضخامت سنج
- دستگاه الکترولیز
- وسیله برش چهارخانه ای (با ٦ لبه برش با فواصل ۱ تا ۲ میلی متر)
- نوار چسب سلولزی- تسا ٤١٠٤ یا مشابه آن
- برس نرم
- بزرگنما با درجه درشت نمایی ٦ برابر (× ٦)
- بزرگنما با درجه درشت نمایی ۲۵ برابر (× ۲۵)
- پنبه یا پارچه نرم
- دستگاه اندازه گیری میزان انعطاف پذیری و پایداری فیلم خشک در برابر گوه ای شدن
- ورق فلزی پوشش داده شده کاملا مسطح و بدون فرم حداکثر به ابعاد ۵۰ در ۱۲۰ میلی متر
- دستگاه جامی شدن گرد یا فنجانی شدن گرد [1]
- ورق فلزی صاف و تخت به ابعاد ٦۵ در ۱۰۰ میلی متر
- اتوکلاو
- قلم سختی سنج [2]
- دستگاه کنگره زنی آزمایشگاه
- دستگاه کشش عمیق و نیمه عمیق
- بسته بندی فلزی یا آزمونه

1- Cupping tester
2- Dur- o- test

- دستگاه آزمون استون
- دستگاه تعیین خلل و فرج
- خلاء سنج- فشارسنج
- در بازکن
- کاغذ صافی
- ابزارآلات فیلم کشی
- ویسکومتر
- صفحه نازک مسی
- پیکنومتر فلزی
- پیکنومتر شیشه ای
- دماسنج با دقت ۰/۲ درجه سانتی گراد و درجه بندی ۰/۲ درجه سانتی گراد
- محفظه کنترل دما یا حمام آب گرم مجهز به ترموستات، قابل تنظیم در ۳۰-۲۵ درجه سانتی گراد با دقت ۰/۱ درجه سانتی گراد
- ظرف مقاوم در برابر نفوذ گرد و غبار
- دستگاه ساده شستشو با آب
- دستگاه یا پمپ ایجاد خلاء یا وسیله کاهش فشار تا کمتر از ۲KPa
- صفحه گریندومتر
- کاپ های مخصوص جاری شدن
- پایه جهت نگه داشتن کاپ و وسیله ای جهت صاف کردن لبه مایع
- میله جهت تراز کردن سطح کاپ ترجیحاً از نوع استوانه ای
- صفحه شیشه ای صاف
- زمان سنج (تایمر) یا وسیله مناسب دیگر با تقسیم بندی ۰/۲ ثانیه یا با دقت ۰/۱ درصد (در زمان ۶۰ دقیقه)
- دستگاه اندازه گیری میزان نوچی فیلم خشک
- دستگاه ضربه با گوی در حال سقوط
- دستگاه ساده شستشو با آب گرم گازدار (برای آزمون مهاجرت کل)
- آون (برای آزمون مهاجرت کل)
- اجاق صفحه ای داغ(برای آزمون مهاجرت کل)

- کروزه پلاتینی (برای آزمون مهاجرت کل)

حداقل مواد شیمیایی مورد نیاز در آزمایشگاه فیزیکوشیمیایی

- ارتوفسفات هیدرات دی سدیم
- اسید سیتریک
- اسید استیک گلاسیال
- اسید لاکتیک
- نمک کلرید سدیم
- کلرید سیستئین
- پتاسیم دی هیدروژن فسفات
- الکل اتیلیک
- محلول بی کربنات سدیم ۲٪
- محلول اکسیتول
- محلول سود ۱۰٪
- محلول سولفات مس اسیدی (۵ آبه)
- چربی حیوانی یا پارافین
- حلال استون با درجه خلوص بالا
- محلول الکترولیت مناسب دستگاه تعیین خلل و فرج
- مخلوط متیلن کلراید و متانول صنعتی به نسبت ۱۰ میلی لیتر متیلن کلراید و ۱ میلی لیتر متانول صنعتی
- محلول سولوسو
- اسید سولفوریک غلیظ (۹۷-۹۵٪)
- آب مقطر (برای آزمون مهاجرت کل)
- هپتان (برای آزمون مهاجرت کل)
- کلروفرم (برای آزمون مهاجرت کل)

یاد آوری ۱

در صورتیکه واحد تولیدی قادر به انجام برخی آزمایشات خاص و همچنین انجام آزمون مهاجرت خاص نباشد ، می تواند ضمن عقد قرارداد ، نمونه های تولیدی بر اساس دستورالعمل و روش اجرایی نمونه برداری و ارسال به آزمایشگاه که توسط کارخانه تهیه می شود را به آزمایشگاههای مورد تائید وزارت بهداشت ارجاع دهد تا مورد آزمایش قرار گرفته و نتایج بصورت مستند تهیه و نگهداری شوند.

یادآوری ۲

انجام آزمون مهاجرت کل توسط واحد تولیدکننده پوشش و درزگیر جهت اخذ پروانه ساخت الزامی است ولی مصرف کننده ظروف باید خود آزمون مهاجرت عمومی را انجام دهند.

۱۰- پیوست اطلاعاتی

- انواع و ویژگی های زرین های مصرفی در پوشش های داخل قوطی

نوع رزین	ساختار	انعطاف پذیری	مقاومت به مواد غذایی
اپوکسی فنولیک	وزن مولکولی بالا و اتصال عرضی با رزین فنولیک رزول	خوب	خیلی خوب
اورگانوسل	PVC که در ورنی مناسب حل شده وبا یک رزین اپوکسی با وزن مولکولی پایین یا رزین اپوکسی نووالاک پایدار شده است. از روغنهای اپوکسی دار نیز میتوان استفاده نمود.	خیلی خوب	خیلی خوب
اپوکسی انیدرید	اپوکسی با وزن مولکولی بالا که با سخت کننده های انیدرید اتصال عرضی شده است.	خوب	خیلی خوب
اپوکسی آمینو	اپوکسی رزین با وزن مولکولی بالا که با رزین آمینو اتصال عرضی شده است. همچنین اپوکسی اکریلیک پایه آبی.	خوب	محدود
پلی استر	رزینهای پلی استری دارای اتصال عرضی با آمین یا رزین فنولیک. می توانند دارای اپوکسی رزین با وزن مولکولی پائین باشد.	خیلی خوب	بستگی به ماده بسته بندی شونده دارد
فنولیک	رزین های فنولیک با خاصیت خود اتصال عرضی	خیلی ضعیف اما کیفیت فیلم وابسته به وزن است	عالی
اولئورزین	روغن ها با منشاء طبیعی و اصلاح شده سنتزی	متغیر	بسته به نوع ماده بسته بندی شونده دارد

- پوششها رنگ نهایی خود را با روشهای مختلفی به دست می آورند.پوششهای ترکیبی با رزین فنولیک ،بعد از پخت معمولاً فام طلایی و در صورت وجود سایر رنگدانه های مجاز تغییراتی از قبیل بژ ، آلومینیوم و امثال آن را خواهند داشت . رنگ حاصله میتواند بعنوان نمایشگر میزان پخت سیستم باشد.

- پوششهای سفید معمولا"با افزایش دی اکسید تیتانیوم به سیستمهای اپوکسی انیدرید و پلی استرها و اورگانوسلها و سایر رزینهای پایه مجاز ساخته می شود.

- رنگدانه آلومینیوم و در برخی از موارد اکسید روی ، که معمولاً به پوششها اضافه می شود ، باعث بروز رنگ در دامنه فام طوسی پوشش میگردد.

- آزمایشات علمی نشان داده است تغییر رنگ (فام)سطح داخلی لاکهای داخل قوطی های پرشده بعلت رنگ پذیری آنها از مواد رنگزای موجود در ماده غذایی مانند لیکوپن (گوجه فرنگی) و ادویه جات (زردچوبه) حاصل میگردد و دارای اثرات منفی بر ماده غذایی و سلامتی انسان نمی باشد.این مواد رنگ زا ترکیبی با سطح پلیمری ایجاد نمیکنند و به راحتی میتوانند با روشهای تجزیه ای از روی سطح جداسازی و مورد شناسایی قرار گیرند . جداسازی این مواد رنگ زا از بدنه لاک میتواند وجود احتمالی سایر عوامل رنگ زای غیر مجاز در ماده غذایی را شناسایی نماید .

- آماده سازی،استعمال و پخت مواد شیمیایی مصرفی در تماس با مواد غذایی توسط تولید کننده بسته بندی فلزی لزوماً باید در تناسب و تابع مشخصات سازنده پوشش بوده و در شرایط تعیین شده صورت پذیرد.
- از آنجائیکه مشخصات کاربری پوشش مانند درجه پخت پوشش ، وابسته به عواملی مانند مشخصات ورق پایه ،ضخامت ورق پایه ، طول کوره ، تعداد زونهای حرارتی کوره ، پاکیزگی ویکتها و دودکش کوره و.....میباشد ، لذا لازم است تا با رعایت تاثیر کلیه عوامل ، از پخت پوشش در دمای مناسب و ضخامت مناسب، اطمینان حاصل گردد. از عوامل بسیار مهم دیگر در حفظ سلامت پوشش، شرایط انبارش و دمای شروع به کار اولیه در خط است . ورود پوشش و پایه فلز مصرفی به خط باید با رعایت رسیدن دمای آن به بالاتر از$^{\circ}$C ۱۰ و کمتر از $^{\circ}$C ۳۰ صورت پذیرد.پس از کسب اطمینان از صحت سیکل پخت، آزمونهای مهاجرت روی پوشش میتوانند انجام گردند.

۱۱- مراجع

۱- آخرین تجدید نظر استاندارد ملی ایران به شماره ۴۹۱۵- روش کلی اندازه گیری وزن مخصوص پودر با استفاده از پیکنومتر

۲- آخرین تجدید نظر استاندارد ملی ایران به شماره ۶۰۸۵- رنگ و جلا- اندازه گیری زمان جاری شدن با استفاده از کاپ

۳- آخرین تجدید نظر استاندارد ملی ایران به شماره ۶۴۶۰- رنگ ها و مرکب چاپ- روش تعیین دانه بندی

۴- آخرین تجدید نظر استاندارد ملی ایران به شماره ۲۵۰۹- بسته بندی – پوشش های مورد مصرف در بسته بندی فلزی- روش های آزمون

۵- آخرین تجدید نظر استاندارد ملی ایران به شماره ۱-۶۴۵۴- رنگ ها و جلاها- روش تعیین دانسیته- قسمت اول: با استفاده از پیکنومتر

۶- آخرین تجدید نظر استاندارد ملی ایران به شماره ۲۵۰۹- بسته بندی- پوشش های مورد مصرف در بسته بندی فلزی موادغذایی و آشامیدنی- روش های آزمون

۷- آخرین تجدید نظر استاندارد ملی ایران به شماره ۲۴۵۵- بسته بندی- پوشش های مورد مصرف در بسته بندی فلزی - ویژگی ها

۸- حداقل ضوابط فنی و بهداشتی برای تأسیس و بهره برداری واحدهای تولیدکننده مواد بسته بندی غذایی، آشامیدنی، آرایشی و بهداشتی (فیلم ها، مقوا،بطری، لاک ها، پوشش ها و ...)، کد PEI/CrV/0034

9- K.T. Peter oldring and nehring ulrich , 2007, packaging materials 7.metal packaging for food stuffs.

10- Code of federal regulations , title 21, volume 3, Rev.1-2007, Sec.177.1210 closures with sealing gaskets for food containers.

11- Code of federal regulations , title 21, volume 3, Rev.1-2007, Sec.175.300 resinous and polymeric coatings .

12- Concil of europe, 2008 , coatings intended to come into contact with food stuffs.

13- Council of europe, 2007, packaging inks applied to the non-food contact surface of food packaging .

14- Commission regulation (EC) No 2023/2006, good manufacturing practice for materials and articles intended to come into contact with food .

15-Consolidated list of C/M/R- substances- relating to points 29,30 and 31 of annex I of directive 76/769/EEC.

[Code of Federal Regulations]
[Title 21, Volume 3]
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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 177 -- INDIRECT FOOD ADDITIVES: POLYMERS

Subpart B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec. 177.1210 Closures with sealing gaskets for food containers.

Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Closures for food containers are manufactured from substances generally recognized as safe for contact with food; substances that are subject to the provisions of prior sanctions; substances authorized by regulations in parts 174, 175, 176, 177, 178 and 179.45 of this chapter; and closure-sealing gaskets, as further prescribed in this section.

(b) Closure-sealing gaskets and overall discs are formulated from substances identified in 175.300(b) of this chapter, with the exception of paragraph (b)(3) (v), (xxxi), and (xxxii) of that section, and from other optional substances, including the following:

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval within the meaning of section 201(s) of the act.

(3) Substances that are the subject of regulations in parts 174, 175, 176, 177, 178 and 179.45 of this chapter and used in accordance with the conditions prescribed.

(4) Substances identified in paragraph (b)(5) of this section, used in amounts not to exceed those required to accomplish the intended physical or technical effect and in conformance with any limitation provided; and further provided that any substance employed in the

production of closure-sealing gasket compositions that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179.45 of this chapter conforms with the identity or specifications prescribed.

(5) Substances that may be employed in the manufacture of closure-sealing gaskets include:

Table 1

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Arachidy-l-behenyl amide (C-Cfatty acid amides)	5 percent.
Azodicarbonamide	1. 2 percent.
	2. 5 percent; for use only in the manufacture of polyethylene complying with item 2.1 in 177.1520(c) of this chapter.
Balata rubber	
Benzyl alcohol	1 percent.
Brominated isobutylene-isoprene copolymers, produced when isobutylene-isoprene copolymers complying with 177.1420(a)(2) are modified by bromination with not more than 2.3 weight-percent of bromine and having a Mooney Viscosity (ML 1+8 (125 deg. C)) of 27 or	

higher. The viscosity is determined by the American Society for Testing and Materials (ASTM) method D 1646-81, "Standard Test Method for Rubber--Viscosity and Vulcanization Characteristics (Mooney Viscometer)," which is incorporated by reference in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2504 and the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:*http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*	
1,3-Butanediol	
Calcium tin stearate	2 percent.
Calcium zinc stearate	Do.
Carbon, activated	1 percent.
Castor oil, hydrogenated	2 percent.
Chlorinated isobutylene-isoprene copolymers complying with 177.1420	
Coco amide (coconut oil fatty acids amides)	2 percent.
Cork (cleaned, granulated)	
Diebenzamide phenyl disulfide	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Di(C, C-alkyl) adipate	Complying with 178.3740 of this chapter; except that, there is no limitation on polymer thickness.

Di-2-ethylhexyl adipate	
Di-2-ethylhexyl sebacate	2 percent.
Di-2-ethylhexyl terephthalate (CAS Reg. No. 006422-86-2).	For use as a plasticizer at levels not exceeding 75 parts per hundred by weight of permitted vinyl chloride homo- and/or copolymer resins used in contact with food of Types I, II, IV-B, VI-A, VI-B, VI-C (up to 15 percent alcohol by volume), VII-B, and VIII described in 176.170(c) of this chapter, table 1, and under conditions of use A through H described

	in 176. 170 (c) of this chapter, table 2.
Dihexyl ester of sodium sulfosuccinate	1 percent.
Diisodecyl phthalate	No limitation on amount used but for use only in closure-sealing gasket compositi ons used in contact with non-fatty foods containing no more than 8 percent of alcohol.
Di-[beta]-naphthyl-*p*-phenylenediamine	1 percent.
Dipentamethylenethiurametetrasulfide	0.4 percent; for use only in vulcanized natural or synthetic rubber gasket compositi ons.
Eicosane (technical grade) (water-white mixture of predominantly straight-chain paraffin hydrocarbons averaging 20 carbon atoms per molecule)	
Epoxidized linseed oil	
Epoxidized linseed oil modified with trimellitic anhydride	
Epoxidized safflower oil	

Epoxidized safflower oil modified with trimellitic anhydride	
Epoxidized soybean oil modified with trimellitic anhydride	
Erucylamide	5 percent.
Ethylene-propylene copolymer	
Ethylene-propylene modified copolymer elastomers produced when ethylene and propylene are copolymerized with 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene. The finished copolymer elastomers so produced shall contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene, and shall have a minimum viscosity average molecular weight of 120,000 as determined by the method described in 177.1520(d)(5), and a minimum Mooney viscosity of 35 as determined by the method described in 177.1520(d)(6)	
Ethylene-vinyl acetate copolymer	
Glyceryl mono-12-hydroxystearate (hydrogenated glyceryl ricinoleate)	2 percent.
Gutta-percha	
Hexamethylenetetramine	1 percent.
Hexylene glycol	0.5 percent.
Isobutylene-isoprene copolymers complying with 177.1420	
Maleic anhydride-polyethylene copolymer	5 percent.
Maleic anhydride-styrene copolymer	Do.
2,2'-Methylenebis[6-(1-methylcylcohexyl)-*p*-cresol]	1 percent.
Mixed octylated diphenylamine (CAS Reg. No. 68411-46-1)	0.1 percent in isobutylene-isoprene and chlorinated isobutylene-isoprene copolymers complying with 177.1420, and brominated isobutylene-isoprene

	copolymers complying with this section.
Napthalene sulfonic acid-formaldehyde condensate, sodium salt	0.2 percent.
Natural rubber (crepe, latex, mechanical dispersions)	
[alpha]-*cis*-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles	0.5 percent.
Oleyl alcohol	1 percent.
4,4'-Oxybis (benzene sulfonyl hydrazide)	0.5 percent.
Paraformaldehyde	1 percent.
Polybutadiene	
Poly-*p*-dinitroso benzene (activator for butyl rubber)	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Polyethylene glycol 400 esters of fatty acids derived from animal and vegetable fats and oils	1 percent.
Polyisobutylene complying with 177.1420	
Polyoxypropylene-polyoxyethylene condensate, average mol. wt. 2750-3000	0.05 percent.
Polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid (CAS Reg. No. 26375-23-5).	For use only: No limitation on amount used, but for use only in closure gasket compositions used in contact

	with food types VI-A and VI-C (up to 15 percent alcohol) under conditions of use D, E, F, and G, as described in 176.170(c) of this chapter, tables 1 and 2, respectively.
Potassium benzoate	1 percent.
Potassium perchlorate	Do.
Potassium propionate	2 percent.
Potassium and sodium persulfate	1 percent.
Resorcinol	0.24 percent; for use only as a reactive adjuvant substance employed in the production of gelatin-bonded cord compositions for use in lining crown closures. The gelatin so

	used shall be technical grade or better.
Rosins and rosin derivatives as defined in 175.300(b)(3)(v) of this chapter for use only in resinous and polymeric coatings on metal substrates; for all other uses as defined in 178.3870 of this chapter	
Sodium cetyl sulfate	1 percent.
Sodium decylbenzenesulfonate	Do.
Sodium decyl sulfate	Do.
Sodium formaldehyde sulfoxylate	0.05 percent.
Sodium lauryl sulfate	1 percent.
Sodium lignin sulfonate	0.2 percent.
Sodium myristyl sulfate (sodium tetradecyl sulfate)	0.6 percent.
Sodium nitrite	0.2 percent; for use only in annular ring gaskets applied in aqueous dispersions to closures for containers having a capacity of not less than 5 gallons.
Sodium*o*-phenylphenate	0.05 percent.
Sodium polyacrylate	5 percent.
Sodium and potassium pentachlorophenate	0.05 percent.

Sodium salt of trisopropyl napthalenesulfonic acid	0.2 percent.
Sodium tridecylsulfate	0.6 percent.
Stearic acid amide	5 percent.
Sulfur	For use only as a vulcanizing agent in vulcanized natural or synthetic rubber gasket compositions at a level not to exceed 4 percent by weight of the elastomer content of the rubber gasket composition.
Tallow, sulfated	1 percent.
Tin-zinc stearate	2 percent.
Tri(mixed mono- and dinonylphenyl) phosphite	1 percent.
Vinyl chloride-vinyl stearate copolymer	
Zinc dibutyldithiocarbamate	0.8 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.

Table 2--Maximum Extractives Tolerances

[In parts per million]

Type of closure-sealing gasket composition	Chloroform fraction of water extractives	Chloroform fraction of heptane extractives	Chloroform fraction of alcohol extractives
1. Plasticized polymers, including unvulcanized or vulcanized or otherwise cured natural and synthetic rubber formed in place as overall discs or annular rings from a hot melt, solution, plastisol, organisol, mechanical dispersion, or latex	50	500	50
2. Preformed overall discs or annular rings of plasticized polymers, including unvulcanized natural or synthetic rubber	50	250	50
3. Preformed overall discs or annular rings of vulcanized plasticized polymers, including natural or synthetic rubber	50	50	50
4. Preformed overall discs or annular rings of polymeric or resinous-coated paper, paperboard, plastic, or metal foil substrates	50	250	50
5. Closures with sealing gaskets or sealing compositions as described in 1, 2, 3, and 4, and including paper, paperboard, and glassine used for dry foods only	([1])	([1])	([1])

[1]Extractability tests not applicable.

(c) The closure assembly to include the sealing gasket or sealing compound, together with any polymeric or resinous coating, film, foil, natural cork, or glass that forms a part of the food-contact surface of the assembly, when extracted on a suitable glass container with a solvent or solvents characterizing the type of foods, and under conditions of time and temperature characterizing the conditions of its use as determined from tables 3 and 4 shall

yield net chloroform-soluble extractives (corrected for zinc as zinc oleate) not to exceed the tolerances specified in table 2, calculated on the basis of the water capacity of the container on which the closure is to be used. Employ the analytical method described in **175.300** of this chapter, adapting the procedural details to make the method applicable to closures; such as, for example, placing the closed glass container on its side to assure contact of the closure's food-contacting surface with the solvent.

Table 3--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 emulsions, high- or low-fat.

B. Oil-in-water emulsions, 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).

Table 4--Test Procedures With Time-Temperature Conditions for Determining Amount of Extractives From Closure-Sealing Gaskets, Using Solvents Simulating Types of Foods and Beverages

Conditions of use	Types of food(see table 3)	Extractant		
		Water[2]	Heptane[1,2]	8 percentalcohol[2]
A. High temperature	I, IV-BIII,	250 deg. F, 2	150 deg. F, 2	

heat-sterilized (e.g., over 212 deg. F)	IV-A, VII	hr.....do	hr	
B. Boiling water-sterilized	IIIII, VII	212 deg. F, 30 min.....do	120 deg. F, 30 min	
C. Hot filled or pasteurized above 150 deg. F	II, IV-BIII, IV-AV	Fill boiling, cool to 100 deg. F.....do	120 deg. F, 15 min.....do	
D. Hot filled or pasteurized below 150 deg. F	II, IV-B, VI-BIII, IV-AVVI-A	150 deg. F, 2 hr.....do	100 deg. F, 30 min.....do	150 deg. F, 2 hr
E. Temperature filled and stored (no thermal treatment in the container)	II, IV-B, VI-BIII, IV-AVVI-A	120 deg. F, 24 hr.....do	70 deg. F, 30 min.....do	120 deg. F, 24 hr.
F. Refrigerated storage (no thermal treatment)	I, II, III, IV-A, IV-B, VI-B, VIIVI-A	70 deg. F, 48 hr	70 deg. F, 30 min	70 deg. F, 48 hr.
G. Frozen storage (no thermal treatment in the container)	I, II, III, IV-B, VII	70 deg. F, 24 hr		

[1]Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.

[2]Time and temperature.

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 22090, May 21, 1982; 49 FR 5748, Feb. 15, 1984; 55 FR 34555, Aug. 23, 1990; 61 FR 14480, Apr. 2, 1996; 65 FR 26745, May 9, 2000; 65 FR 52908, Aug. 31, 2000; 70 FR 67651, Nov. 8, 2005]

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 175 -- INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

Subpart C--Substances for Use as Components of Coatings

Sec. 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between the food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymerized substances.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and

polymeric coatings that is the subject of a regulation in subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b)(3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.

Candlenut.

Castor (including dehydrated).

Chinawood (tung).

Coconut.

Corn.

Cottonseed.

Fish (refined).

Hempseed.

Linseed.

Oiticica.

Perilla.

Poppyseed.

Pumpkinseed.

Safflower.

Sesame.

Soybean.

Sunflower.

Tall oil.

Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by

filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction, or modified by combination with maleic anhydride.

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in paragraph (b)(3)(i) of this section to form esters with:

Butylene glycol.

Ethylene glycol.

Pentaerythritol.

Polyethylene glycol.

Polypropylene glycol.

Propylene glycol.

Sorbitol.

Trimethylol ethane.

Trimethylol propane.

(iii) Synthetic drying oils, as the basic polymer:

Butadiene and methylstyrene copolymer.

Butadiene and styrene copolymer, blown or unblown.

Maleic anhydride adduct of butadiene styrene.

Polybutadiene.

(iv) Natural fossil resins, as the basic resin:

Copal.

Damar.

Elemi.

Gilsonite.

Glycerol ester of damar, copal, elemi, and sandarac.

Sandarac.

Shellac.

Utah coal resin.

(v) Rosins and rosin derivatives, with or without modification by polymerization, isomerization, incidental decarboxylation, and/or hydrogenation, as follows:

(*a*) Rosins, refined to color grade of K or paler:

Gum rosin.

Tall oil rosin.

Wood rosin.

(*b*) Rosin esters formed by reacting rosin (paragraph (b)(3)(v)(*a*) of this section) with:

4,4' -*sec*- Butylidenediphenol-epichlorohydrin (epoxy).

Diethylene glycol.

Ethylene glycol.

Glycerol.

4,4'-Isopropylidenediphenol-epichlorohydrin (epoxy).

Methyl alcohol.

Pentaerythritol.

(*c*) Rosin esters (paragraph (b)(3)(v)(*b*) of this section) modified by reaction with:

Maleic anhydride.

o-, *m*-, and *p*- substituted phenol-formaldehydes listed in paragraph (b)(3)(vi) of this section.

Phenol-formaldehyde.

(*d*) Rosin salts:

Calcium resinate (limed rosin).

Zinc resinate.

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(*a*) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols.

p-tert- Amylphenol.

4,4' *-sec-* Butylidenediphenol.

p-tert- Butylphenol.

o-, *m-*, and *p-* Cresol.

p- Cyclohexylphenol.

4,4'-Isopropylidenediphenol.

p- Nonylphenol.

p- Octylphenol.

3-Pentadecyl phenol mixture obtained from cashew nut shell liquid.

Phenol.

Phenyl *o-* cresol.

p- Phenylphenol.

Xylenol.

(*b*) Adjunct for phenolic resins: Aluminum butylate.

(vii) Polyester resins (including alkyd-type), as the basic polymers, formed as esters of acids listed in paragraph (b)(3)(vii) (*a*) and (*b*) of this section by reaction with alcohols in paragraph (b)(3)(vii) (*c*) and (*d*) of this section.

(*a*) Polybasic acids:

Adipic.

1,4-cyclohexanedicarboxylic (CAS Reg. No. 1076-97-7).

Dimerized fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.

Fumaric.

Isophthalic.

Maleic.

2,6-Naphthalenedicarboxylic.

2,6-Naphthalenedicarboxylic, dimethyl ester.

Orthophthalic.

Sebacic.

Terephthalic.

Terpene-maleic acid adduct.

Trimellitic.

(*b*) Monobasic acids:

Benzoic acid.

4,4-Bis(4'-hydroxyphenyl)-pentanoic acid.

tert- Butyl benzoic acid.

Fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.

Rosins listed in paragraph (b)(3)(v)(*a*) of this section, for use only as reactants in oil-based or fatty acid-based alkyd resins.

(*c*) Polyhydric alcohols:

Butylene glycol.

Diethylene glycol.

2,2-Dimethyl-1,3-propanediol for use only in forming polyester resins for coatings intended for use in contact with non-alcoholic foods.

Ethylene glycol.

Glycerol.

Mannitol.

percent C 14 carbon atoms, for use only in coatings that are intended for contact with dry bulk foods at room temperature.

4,4' -*sec*- Butylidenediphenol-epichlorohydrin.

4,4' -*sec*- Butylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4' -*sec*- Butylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:

Allyl ether of mono-, di-, or trimethylol phenol.

4,4' -*sec*- Butylidenediphenol-formaldehyde.

4,4'-Isopropylidenediphenol-formaldehyde.

Melamine-formaldehyde.

Phenol-formaldehyde.

Urea-formaldehyde.

Epoxidized polybutadiene.

Glycidyl ethers formed by reacting phenolnovolak resins with epichlorohydrin.

4,4'-Isopropylidenediphenol-epichlorohydrin.

4,4'-Isopropylidenediphenol-epichlorohydrin reacted with one or more of the drying oils or fatty acids listed in paragraph (b)(3)(i) of this section.

4,4'-Isopropylidenediphenol-epichlorohydrin chemically treated with one or more of the following substances:

Allyl ether of mono-, di-, or trimethylol phenol.

4,4' -*sec*- Butylidenediphenol-formaldehyde.

4,4'-Isopropylidenediphenol-formaldehyde.

Melamine-formaldehyde.

2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene>bisoxirane, CAS Reg. No. 71033-08-4, for use only in coatings intended for contact with bulk dry foods at temperatures below 100 deg. F.

Phenol-formaldehyde.

Urea-formaldehyde.

(*b*) Catalysts and cross-linking agents for epoxy resins:

3-(Aminomethyl)-3,5,5-trimethylcyclohexylamine reacted with phenol and formaldehyde in a ratio of 2.6:1.0:2.0, for use only in coatings intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Category I and Category VIII, at temperatures not exceeding 88 deg. C (190 deg. F).

N- *Beta* -(aminoethyl)- *gamma* -aminopropyltrimethoxysilane (CAS Reg. No. 1760-24-3), for use only in coatings at a level not to exceed 1.3 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Benzyl alcohol (CAS Reg. No. 100-51-6), for use only in coatings at a level not to exceed 4 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Catalysts and cross-linking agents for epoxy resins:

3-Aminomethyl-3,5,5-trimethylcyclohexylamine (CAS Reg. No. 2855-0913-092).

Cyanoguanidine.

Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

3-Diethylaminopropylamine (CAS Reg. No. 104-78-9), for use in

[alpha]-Methyl glucoside.

Pentaerythritol.

Propylene glycol.

Sorbitol.

Triethylene glycol, for use as a component in polyester resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Trimethylol ethane.

Trimethylol propane.

(*d*) Monohydric alcohols:

Cetyl alcohol.

Decyl alcohol.

Lauryl alcohol.

Myristyl alcohol.

Octyl alcohol.

Stearyl alcohol.

(*e*) Catalysts:

Dibutyltin oxide (CAS Reg. No. 818-08-6), not to exceed 0.2 percent of the polyester resin.

Hydroxybutyltin oxide (CAS Reg. No. 2273-43-0), not to exceed 0.2 percent of the polyester resin.

Monobutyltin tris(2-ethylhexoate) (CAS Reg. No. 23850-94-4), not to exceed 0.2 percent of the polyester resin.

(viii) Epoxy resins, catalysts, and adjuncts:

(*a*) Epoxy resins, as the basic polymer:

(Alkoxy C 10 -C 16)-2,3-epoxypropane, in which the alkyl groups are even numbered and consist of a maximum of 1 percent C 10 carbon atoms and a minimum of 48 percent C 12 carbon atoms and a minimum of 18

coatings at a level not to exceed 6 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Diethylenetriamine.

Diphenylamine.

Ethylenediamine.

Isophthalyl dihydrazide for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

4,4'-Methylenedianiline, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

N- Oleyl-1,3-propanediamine with not more than 10 percent by weight of diethylaminoethanol.

3-Pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 (CAS Reg. No. 68413-28-5).

Polyamine produced when 1 mole of the chlorohydrin diether of polyethylene glycol 400 is made to react under dehydrohalogenating conditions with 2 moles of *N*- octadecyltrimethylenediamine for use only in coatings that are subject to the provisions of paragraph (c) (3) or (4) of this section and that contact food at temperatures not to exceed room temperature.

Polyethylenepolyamine (CAS Reg. No. 68131-73-7), for use only in coatings intended for repeated use in contact with food, at temperatures not to exceed 180 deg. F (82 deg. C).

Salicylic acid, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Salicylic acid (CAS Reg. No. 69-72-7), for use only in coatings at a level not to exceed 0.35 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of

the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Stannous 2-ethylhexanoate for use only as a catalyst at a level not to exceed 1 percent by weight of the resin used in coatings that are intended for contact with food under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

Styrene oxide, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.

Tetraethylenepentamine.

Tetraethylenepentamine reacted with equimolar quantities of fatty acids.

Tri(dimethylaminomethyl) phenol and its salts prepared from the fatty acid moieties of the salts listed in paragraph (b)(3)(xxii)(*b*) of this section, for use only in coatings subject to the provisions of paragraph (c) (3) or (4) of this section.

Triethylenetetramine.

Trimellitic anhydride (CAS Reg. No. 552-30-7) for use only as a cross-linking agent at a level not to exceed 15 percent by weight of the resin in contact with food under all conditions of use, except that resins intended for use with foods containing more than 8 percent alcohol must contact such food only under conditions of use D, E, F, and G described in table 2 of paragraph (d) of this section.

Trimellitic anhydride adducts of ethylene glycol and glycerol, prepared by the reaction of 1 mole of trimellitic anhydride with 0.4-0.6 mole of ethylene glycol and 0.04-0.12 mole of glycerol, for use only as a cross-linking agent at a level not to exceed 10 percent by weight of the cured coating, provided that the cured coating only contacts food containing not more than 8 percent alcohol.

Meta-Xylylenediamine (1,3-benzenedimethanamine, CAS Reg. No. 1477-55-0), for use only in coatings at a level not to exceed 3 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E or F as described in table 2 of paragraph

(d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Para-Xylylenediamine (1,4 benzenedimethanamine, CAS Reg. No. 539-48-0), for use only in coatings at a level not to exceed 0.6 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E and F as described in table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

(*c*) Adjuncts for epoxy resins:

Aluminum butylate.

Benzoic acid, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

Polyamides from dimerized vegetable oils and the amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section, as the basic polymer.

Silane coupled silica, prepared from the reaction of microcrystalline quartz with *N-beta-* (*N-* vinylbenzylamino) ethyl- *gamma-* aminopropyltrimethoxy silane, monohydrogen chloride, for use only in coatings intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Category I and Category VIII, at temperatures not exceeding 88 deg. C (190 deg. F).

Succinic anhydride, for use as a component in epoxy resins for coatings not exceeding a coating weight of 4 milligrams per square inch, and that are intended for contact under conditions of use D, E, F or G described in table 2 of paragraph (d) of this section with alcoholic beverages containing less than 8 percent alcohol.

(ix) Coumarone-indene resin, as the basic polymer.

(x) Petroleum hydrocarbon resin (cyclopentadiene type), as the basic polymer.

(xi) Terpene resins, as the basic polymer, from one or more of the following:

Dipentene.

Hydrogenated dipentene resin (CAS Reg. No. 106168-39-2). For use only with coatings in contact with acidic and aqueous foods.

Hydrogenated- *beta* -pinene- *alpha* -pinene-dipentene copolymer resin (CAS Reg. No. 106168-37-0). For use only with coatings in contact with acidic and aqueous foods.

[alpha]-Pinene.

[beta]-Pinene.

(xii) Urea-formaldehyde, resins and their curing catalyst:

(*a*) Urea-formaldehyde resins, as the basic polymer:

Urea-formaldehyde.

Urea-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

Urea-formaldehyde chemically modified with one or more of the amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section.

(*b*) Curing (cross-linking) catalyst for urea-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiii) Triazine-formaldehyde resins and their curing catalyst:

(*a*) Triazine-formaldehyde resins, as the basic polymer:

Benzoguanamine-formaldehyde.

Melamine-formaldehyde.

Melamine-formaldehyde chemically modified with one or more of the following amine catalysts:

Amine catalysts listed in paragraph (b)(3)(viii)(*b*) of this section.

Dimethylamine-2-methyl-1-propanol.

Methylpropanolamine.

Triethanolamine.

Melamine-formaldehyde chemically modified with methyl, ethyl, propyl, isopropyl, butyl, or isobutyl alcohol.

(*b*) Curing (cross-linking) catalyst for triazine-formaldehyde resins:

Dodecyl benzenesulfonic acid (C.A. Registry No. 27176-87-0).

(xiv) Modifiers (for oils and alkyds, including polyesters), as the basic polymer:

Butyl methacrylate.

Cyclopentadiene.

Methyl, ethyl, butyl, or octyl esters of acrylic acid.

Methyl methacrylate.

Styrene.

Vinyl toluene.

(xv) Vinyl resinous substance, as the basic polymers:

Polyvinyl acetate.

Polyvinyl alcohol.

Polyvinyl butyral.

Polyvinyl chloride.

Polyvinyl formal.

Polyvinylidene chloride.

Polyvinyl pyrrolidone.

Polyvinyl stearate.

Vinyl chloride-acetate-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.1 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer for use in coatings for containers.

Vinyl chloride-acetate, hydroxyl-modified copolymer.

Vinyl chloride-acetate, hydroxyl-modified copolymer, reacted with trimellitic anhydride.

Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed.

Vinyl chloride copolymerized with one or more of the following substances:

Acrylonitrile.

Fumaric acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.

Maleic acid and/or its methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, or octyl esters.

5-Norbornene-2,3-dicarboxylic acid, mono- *n*- butyl ester; for use such that the finished vinyl chloride copolymers contain not more than 4 weight percent of total polymer units derived from this comonomer.

Vinyl acetate.

Vinylidene chloride.

Vinyl chloride-vinylidene chloride-2,3-epoxypropyl methacrylate copolymers containing not more than 10 weight percent of total polymer units derived from 2,3-epoxypropyl methacrylate and not more than 0.05 weight percent of unreacted 2,3-epoxypropyl methacrylate monomer based on polymer solids for use only in coatings for containers intended for contact with foods under conditions B, C, D, E, F, G, or H described in table 2 of paragraph (d) of this section.

(xvi) Cellulosics, as the basic polymer:

Carboxymethylcellulose.

Cellulose acetate.

Cellulose acetate-butyrate.

Cellulose acetate-propionate.

Ethylcellulose.

Ethyl hydroxyethylcellulose.

Hydroxyethylcellulose.

Hydroxypropyl methylcellulose.

Methylcellulose.

Nitrocellulose.

(xvii) Styrene polymers, as the basic polymer:

Polystyrene.

[alpha]-Methyl styrene polymer.

Styrene copolymerized with one or more of the following:

Acrylonitrile.

[alpha]-Methylstyrene.

(xviii) Polyethylene and its copolymers as the basic polymer:

Ethylene-ethyl acrylate copolymer.

Ethylene-isobutyl acrylate copolymers containing no more than 35 weight percent of total polymer units derived from isobutyl acrylate.

Ethylene-vinyl acetate copolymer.

Polyethylene.

(xix) Polypropylene as the basic polymer:

Polypropylene.

Maleic anhydride adduct of polypropylene The polypropylene used in the manufacture of the adduct complies with 177.1520(c), item 1.1; and the adduct has a maximum combined maleic anhydride content of 0.8 percent and a minimum intrinsic viscosity of 0.9, determined at 135 deg. C on a 0.1 percent solution of the modified polypropylene in decahydronaphthalene as determined by a method titled "Method for Determination of Intrinsic Viscosity of Maleic Anhydride Adduct of Polypropylene," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(xx) Acrylics and their copolymers, as the basic polymer:

Acrylamide with ethylacrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butanol.

Acrylic acid and the following esters thereof:

Ethyl.

Methyl.

Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates.

Butyl acrylate-styrene-methacrylic acid-hydroxypropyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxypropyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates and that are intended for contact, under condition of use D, E, F, or G described in table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

Ethyl acrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(*a*) of this section.

Ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii)(*a*) of this section.

2-Ethylhexyl acrylate-ethyl acrylate copolymers prepared by copolymerization of 2-ethylhexyl acrylate and ethyl acrylate in a 7/3 weight ratio and having a number average molecular weight range of 5,800 to 6,500 and a refractive index, *n* D25 deg. (40 percent in 2,2,4-trimethyl pentane) of 1.4130-1.4190; for use as a modifier for nylon resins complying with 177.1500 of this chapter and for phenolic and epoxy resins listed in paragraph (b)(3) (vi) and (viii) of this section, respectively, at a level not to exceed 1.5 percent of the coating.

2-Ethylhexyl acrylate-methyl methacrylate-acrylic acid copolymers for use only as modifiers for epoxy resins listed in paragraph (b)(3)(viii) of this section.

Methacrylic acid and the following esters thereof:

Butyl.

Ethyl.

Methyl.

Methacrylic acid or its ethyl and methyl esters copolymerized with one or more of the following:

Acrylic acid.

Ethyl acrylate.

Methyl acrylate.

n -Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 2 weight percent of total polymer units derived from methacrylic acid and containing no more than 9.5 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings in contact with dry food (food type VIII in table 1 of paragraph (d) of this section). 2-(Dimethylamino) ethanol (C.A.S. Registry No. 108-01-0) may be employed as an optional adjuvant substance limited to no more than 2 weight percent based on polymer solids in the coating emulsion.

Styrene polymers made by the polymerization of any combination of styrene or alpha methyl styrene with acrylic acid, methacrylic acid, 2-ethyl hexyl acrylate, methyl methacrylate, and butyl acrylate. The styrene and alpha methyl styrene, individually, may constitute from 0 to 80 weight percent of the polymer. The other monomers, individually, may be from 0 to 40 weight percent of the polymer. The polymer number average molecular weight (M_n) shall be at least 2,000 (as determined by gel permeation chromatography). The acid number of the polymer shall be less than 250. The monomer content shall be less than 0.5 percent. The polymers are for use only in contact with food of Types IV-A, V, VII in table 1 of paragraph (d) of this section, under use conditions E through G in table 2 of paragraph (d), and with food of Type VIII without use temperature restriction.

(xxi) Elastomers, as the basic polymer:

Butadiene-acrylonitrile copolymer.

Butadiene-acrylonitrile-styrene copolymer.

Butadiene-styrene copolymer.

Butyl rubber.

Chlorinated rubber.

2-Chloro-1,3-butadiene (neoprene).

Natural rubber (natural latex or natural latex solids, smoked or unsmoked).

Polyisobutylene.

Rubber hydrochloride.

Styrene-isobutylene copolymer.

(xxii) Driers made by reaction of a metal from paragraph (b)(3)(xxii)(*a*) of this section with acid, to form the salt listed in paragraph (b)(3)(xxii)(*b*) of this section:

(*a*) Metals:

Aluminum.

Calcium.

Cerium.

Cobalt.

Iron.

Lithium.

Magnesium.

Manganese.

Zinc.

Zirconium.

(*b*) Salts:

Caprate.

Caprylate.

Isodecanoate.

Linoleate.

Naphthenate.

Neodecanoate.

Octoate (2-ethylhexoate).

Oleate.

Palmitate.

Resinate.

Ricinoleate.

Soyate.

Stearate.

Tallate.

(xxiii) Waxes:

Paraffin, Type I.

Paraffin, Type II.

Polyethylene.

Sperm oil.

Spermaceti.

(xxiv) Plasticizers:

Acetyl tributyl citrate.

Acetyl triethyl citrate.

Butyl phthalyl butyl glycolate.

Butyl stearate.

p-tert -Butyl phenyl salicylate.

Dibutyl sebacate.

Diethyl phthalate.

Diisobutyl adipate.

Diisooctyl phthalate.

Epoxidized soybean oil (iodine number maximum 14; oxirane oxygen content 6% minimum), as the basic polymer.

Ethyl phthalyl ethyl glycolate.

2-Ethylhexyl diphenyl phosphate.

di-2-Ethylhexyl phthalate.

Glycerol.

Glyceryl monooleate.

Glyceryl triacetate.

Monoisopropyl citrate.

Propylene glycol.

Sorbitol.

Mono-, di-, and tristearyl citrate.

Triethyl citrate.

Triethylene glycol.

3-(2-Xenolyl)-1,2-epoxypropane.

(xxv) Release agents, as the basic polymer, when applicable:

N,N'- Dioleoylethylenediamine (CAS Reg. No. 110-31-6) for use only in ionomeric resins complying with 177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with 177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.

N,N '-Distearoyl ethylenediamine.

Linoleic acid amide.

Oleic acid amide.

Palmitic acid amide.

Petrolatum.

Polyethylene wax.

Polyoxyethylene glycol monooleate (mol. wt. of the polyoxyethylene glycol moiety greater than 300).

Polytetrafluoroethylene.

Silicones (not less than 300 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

Silicones (not less than 100 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes limited to use only on metal substrates. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

(xxvi) Colorants used in accordance with 178.3297 of this chapter.

(xxvii) Surface lubricants:

Cottonseed oil and other edible oils.

Dibutyl sebacate.

Dioctyl sebacate.

Glyceryl monostearate.

Lanolin.

Mineral oil, white.

Palm oil.

Paraffin, Type I.

Paraffin, Type II.

Petrolatum.

Stearic acid.

(xxviii) Silicones and their curing catalysts:

(*a*) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

Siloxane resins originating from the platinum-catalyzed reaction

product of vinyl-containing dimethylpolysiloxane (CAS Reg. No. 68083-18-1 and CAS Reg. No. 68083-19-2) with methylhydrogen polysiloxane (CAS Reg. No. 63148-57-2) and dimethylmethylhydrogen polysiloxane (CAS Reg. No. 68037-59-2), where the platinum content does not exceed 150 parts per million. The following substances may be used as optional polymerization inhibitors:

3,5-Dimethyl-1-hexyne-3-ol (CAS Reg. No. 107-54-0), at a level not to exceed 0.53 weight-percent;

1-Ethynylcyclohexene (CAS Reg. No. 931-49-7), at a level not to exceed 0.64 weight-percent;

Bis(methoxymethyl)ethyl maleate (CAS Reg. No. 102054-10-4), at a level not to exceed 1.0 weight-percent;

Methylvinyl cyclosiloxane (CAS Reg. No. 68082-23-5); and

Tetramethyltetravinylcyclotetrasiloxane (CAS Reg. No. 2554-06-5).

(*b*) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.

Stannous oleate.

Tetrabutyl titanate.

(xxix) Surface active agents:

Ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol (CAS Reg. No. 9014-85-1).

Poly[2-(diethylamino) ethyl methacrylate] phosphate (minimum intrinsic viscosity in water at 25 deg. C is not less than 9.0 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to use at levels not to exceed 0.1 percent by weight of the copolymers.

Sodium dioctyl sulfosuccinate.

Sodium dodecylbenzenesulfonate

Sodium lauryl sulfate.

2,4,7,9-Tetramethyl-5-decyn-4,7-diol (C.A.S. Reg. No. 126-86-3), for use only in can coatings which are subsequently dried and cured at temperatures of at least 193 deg. C (380 deg. F) for 4 minutes.

(xxx) Antioxidants:

Butylated hydroxyanisole.

Butylated hydroxytoluene.

Gum guaiac.

Dilauryl thiodipropionate.

Nordihydroguaiaretic acid.

Propyl gallate.

Distearyl thiodipropionate.

Thiodipropionic acid.

2,4,5-Trihydroxybutyrophenone.

(xxxi) Can end cements (sealing compounds used for sealing can ends only): In addition to the substances listed in paragraph (b) of this section and those listed in 177.1210(b)(5) of this chapter, the following may be used:

Butadiene-styrene-divinylbenzene copolymer (CAS Reg. No. 26471-45-4) for use only at levels not to exceed 23.8 percent by weight of the cement solids in can end cements.

Butadiene-styrene-fumaric acid copolymer.

4,4'-Butylidenebis (6 -*tert*- butyl -*m*- cresol).

Dibenzamido phenyl disulfide.

Di-[beta]-naphthyl phenylenediamine.

Dipentamethylene thiuram tetrasulfide.

Isobutylene-isoprene-divinylbenzene copolymers for use only at levels not to exceed 15 percent by weight of the dry cement composition.

Naphthalene sulfonic acid-formaldehyde condensate, sodium salt, for use only at levels not to exceed 0.6 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium decylbenzene sulfonate.

Sodium nitrite for use only at levels not to exceed 0.3 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.

Sodium phenylphenate.

Styrene-maleic anhydride resin, partial methyl and butyl (*sec* - or *iso* -) esters, for use only at levels not in excess of 3 percent of the cement solids in can end cement formulations.

Tetrasodium EDTA (tetrasodium ethylene-diaminetetraacetate).

Tri (mixed mono- and dinonylphenyl) phosphite.

Zinc dibutyldithiocarbamate.

(xxxii) Side seam cements: In addition to the substances listed in paragraph (b)(3) (i) to (xxx), inclusive, of this section, the following may be used.

p-tert- Butyl perbenzoate as a catalyst for epoxy resin.

epsilon- Caprolactam-(ethylene-ethyl acrylate) graft polymer.

Dicumyl peroxide for use only as polymerization catalyst.

4-(Diiodomethylsulfonyl) toluene (CAS Reg. No. 20018-09-1) for use as a preservative at a level not to exceed 0.3 percent by weight in can-sealing cements.

Diisodecyl phthalate for use only as plasticizer in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under Categories I, II, and VI.

4,4'-Bis(*alpha,alpha* -dimethylbenzyl)diphenylamine, CAS Reg. No. 10081-67-1.

Ethyl toluene sulfonamide.

Triethylene glycol methacrylate for use only as polymerization cross-linking agent in side seam cements for containers intended for use in contact with food only of the types identified in paragraph (d) of this section, table 1, under Categories I, II, and VI.

Urea.

(xxxiii) Miscellaneous materials:

Ammonium citrate.

Ammonium potassium phosphate.

Bentonite, modified by reaction with benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 71011-24-0). For use only as a rheological agent in coatings intended to contact food under repeated use conditions.

Bentonite, modified by reaction with sodium stearate and benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 121888-68-4). For use as a rheological agent only in coatings intended to contact dry food under repeated-use conditions.

Calcium acetate.

Calcium ethyl acetoacetate.

Calcium glycerophosphate.

Calcium, sodium, and potassium oleates.

Calcium, sodium, and potassium ricinoleates.

Calcium, sodium, and potassium stearates.

Castor oil, hydrogenated.

Castor oil, hydrogenated polymer with ethylenediamine, 12-hydroxyoctadecanoic acid and sebacic acid (CAS Reg. No. 68604-06-8). The condensation product formed by the reaction of hydrogenated castor oil with polyamide derived from ethylenediamine, sebacic acid and 12-hydroxystearic acid, for use only in coatings at a level not to exceed 3.2 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in

N,N'- Hexamethylenebis(3,5-di- *tert* -butyl-4-hydroxyhydrocinnamide), CAS Reg. No. 23128-74-7.

Polyamides consisting of the following:

Copolymer of *omega*- laurolactam and *espilon*- caprolactam, CAS Reg. No. 25191-04-2 (Nylon 12/6).

Homopolymer of *omega* -aminododecanoic acid, CAS Reg. No. 24937-16-4.

Homopolymer of *omega*- laurolactam, CAS Reg. No. 25038-74-8 (Nylon 12).

Polyamides derived from the following acids and amines:

Acids:

Adipic.

Azelaic.

Sebacic.

Vegetable oil acids (with or without dimerization).

Amines:

Diethylenetriamine.

Diphenylamine.

Ethylenediamine.

Hexamethylenediamine.

Tetraethylenepentamine.

Triethylenetetramine.

Polypropylene glycol CAS Reg. No. 25322-69-4.

Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.

Tetrakis [methylene(3,5-di- *tert*- butyl-4-hydroxyhydrocinnamate)]methane, CAS Reg. No. 6683-19-8.

Toluene sulfonamide formaldehyde resin (basic polymer).

table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

Castor oil, sulfated, sodium salt (CAS Reg. No. 68187-76-8), for use only in coatings for containers intended for repeated use.

Cetyl alcohol.

5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2) and optionally containing magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight). For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulations.

Cyclohexanone-formaldehyde resin produced when 1 mole of cyclohexanone is made to react with 1.65 moles of formaldehyde such that the finished resin has an average molecular weight of 600-610 as determined by ASTM method D2503-82, "Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. For use only in contact with nonalcoholic and nonfatty foods under conditions of use E, F, and G, described in table 2 of paragraph (d) this section.

Decyl alcohol.

1,2-Dibromo-2,4-dicyanobutane (CAS Reg No. 35691-65-7). For use as an antimicrobial agent at levels not to exceed 500 milligrams per kilogram in emulsion-based silicone coatings.

Disodium hydrogen phosphate.

Ethyl acetoacetate.

Hectorite, modified by reaction with a mixture of benzyl methyl dialkyl ammonium chloride and dimethyl dialkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow (CAS Reg. No. 121888-67-3). For use as a rheological agent only in coatings intended to contact dry food under repeated-use conditions.

Lauryl alcohol.

Lecithin.

Magnesium, sodium, and potassium citrate.

Magnesium glycerophosphate.

Magnesium stearate.

Mono-, di-, and tricalcium phosphate.

Monodibutylamine pyrophosphate as sequestrant for iron.

Mono-, di-, and trimagnesium phosphate.

Myristyl alcohol.

Octyl alcohol.

Phosphoric acid.

Polybutene, hydrogenated; complying with the identity and limitations prescribed by 178.3740 of this chapter.

Poly(ethylene oxide).

Siloxanes and silicones, dimethyl, 3-hydroxypropyl group-terminated, diesters with poly(2-oxepanone), diacetates (CAS Reg. No. 116810-47-0) at a level not to exceed 0.025 weight percent of the finished coating having no greater than a 0.5 mil thickness for use as a component of polyester, epoxy, and acrylic coatings complying with paragraphs (b)(3)(vii), (viii), and (xx) of this section, respectively.

Silver chloride-coated titanium dioxide for use only as a preservative in latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.

Sodium pyrophosphate.

Stannous chloride.

Stannous stearate.

Stannous sulfate.

Stearyl alcohol.

2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on metal under conditions of use E, F, and G described in table 2 of paragraph (d) of this section, and

limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

Tetrasodium pyrophosphate.

Tridecyl alcohol produced from tetrapropylene by the oxo process, for use only as a processing aid in polyvinyl chloride resins.

Trimethylolpropane (CAS Reg. No. 77-99-6). For use as a pigment dispersant at levels not to exceed 0.45 percent by weight of the pigment.

Vinyl acetate-dibutyl maleate copolymers produced when vinyl acetate and dibutyl maleate are copolymerized with or without one of the monomers: Acrylic acid or glycidyl methacrylate. For use only in coatings for metal foil used in contact with foods that are dry solids with the surface containing no free fat or oil. The finished copolymers shall contain at least 50 weight-percent of polymer units derived from vinyl acetate and shall contain no more than 5 weight-percent of total polymer units derived from acrylic acid or glycidyl methacrylate.

(xxxiv) Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine, as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature.

(xxxv) Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent of monomer acids), ethylenediamine, and 4,4-bis (4-hydroxyphenyl) pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins); as the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.

(xxxvi) Methacrylonitrile grafted polybutadiene copolymers containing no more than 41 weight percent of total polymer units derived from methacrylonitrile; for use only in coatings that are intended for contact, under conditions of use D, E, F, or G described in table 2 of paragraph (d) of this section, with food containing no more than 8 percent of alcohol.

(xxxvii) Polymeric resin as a coating component prepared from terephthalic acid, isophthalic acid, succinic anhydride, ethylene glycol, diethylene glycol, and 2,2-dimethyl-1,3-propanediol for use in contact with aqueous foods and alcoholic foods containing not more than 20 percent (by volume) of alcohol under conditions of use D, E, F, and G described in table 2 of 176.170 of this chapter. The resin shall contain no more than 30 weight percent of 2,2-dimethyl-1,3-propanediol.

(c) The coating in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of paragraph (d) of this section, shall yield chloroform-soluble extractives, corrected for zinc extractives as zinc oleate, not to exceed the following:

(1) From a coating intended for or employed as a component of a container not to exceed 1 gallon and intended for one-time use, not to exceed 0.5 milligram per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container, in milligrams, divided by the area of the food-contact surface of the container in square inches. From a fabricated container conforming with the description in this paragraph (c)(1), the extractives shall not exceed 0.5 milligram per square inch of food-contact surface nor exceed 50 parts per million of the water capacity of the container as determined by the methods provided in paragraph (e) of this section.

(2) From a coating intended for or employed as a component of a container having a capacity in excess of 1 gallon and intended for one-time use, not to exceed 1.8 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(3) From a coating intended for or employed as a component of a container for repeated use, not to exceed 18 milligrams per square inch nor to exceed that amount as milligrams per square inch that would equal 0.005 percent of the water capacity of the container in milligrams, divided by the area of the food-contact surface of the container in square inches.

(4) From coating intended for repeated use, and employed other than as a component of a container, not to exceed 18 milligrams per square inch of coated surface.

(d) Tables:

Table 1--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).

Table 2--Test Procedures for Determining the Amount of Extractives From Resinous or Polymeric Coatings, Using Solvents Simulating Types of Foods and Beverages

Condition of use	Types of food (see table 1)	Extractant		
		Water (time and temperature)	Heptane[1,2](time and temperature)	8 percent alcohol (time and temperature)
A. High temperature heat-sterilized (e.g., over 212 deg. F)	I, IV-BIII, IV-A, VII	250 deg. F, 2 hr.....do	150 deg. F, 2 hr	
B. Boiling water sterilized	IIIII, VII	212 deg. F, 30 min.....do	120 deg. F, 30 min	
C. Hot filled or pasteurized above 150 deg. F	II, IV-B	Fill boiling, cool to 100 deg. F		
	III, IV-AV	.....do	120 deg. F, 15 min.....do	
D. Hot filled or pasteurized below 150 deg. F	II, IV-B, VI-BIII, IV-AVVI-A	150 deg. F, 2 hr.....do	100 deg. F, 30 min.....do	150 deg. F, 2 hr
E. Room temperature filled and stored (no	I, II, IV-B, VI-	120 deg. F, 24 hr.....do	70 deg. F, 30 min.....do	120 deg. F, 24 hr

thermal treatment in the container)	BIII, IV-AV, VIIVI-A			
F. Refrigerated storage, no thermal treatment in the container)	I, II, III, IV-A, IV-B, VI-B, VIIVI-A	70 deg. F, 48 hr		70 deg. F, 48 hr
G. Frozen storage (no thermal treatment in the container)	I, II, III, IV-B, VII	70 deg. F, 24 hr		
H. 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	I, II, IV-B	212 deg. F, 30 min		
2. Aqueous, high or low free oil or fat	III, IV-A, VII	.....do	120 deg. F, 30 min	

[1]Heptane extractant not to be used on wax-lined containers.

[2]Heptane extractivity results must be divided by a factor of five in arriving at the extractivity for a food product.

(e) *Analytical methods* --(1) *Selection of extractability conditions.* First ascertain the type of food product (table 1, paragraph (d) of this section) that is being packed commercially in the test container and the normal conditions of thermal treatment used in packaging the type of food involved. Using table 2 (paragraph (d) of this section), select the food-simulating solvent or solvents (demineralized distilled water, heptane, and/or 8 percent ethyl alcohol) and the time-temperature exaggerations of the container-use conditions. Aqueous products (Types I, II, IV-B, and VI-B) require only a water-extractability test at the temperature and time conditions shown for the most severe "conditions of use." Aqueous products with free oil or fat, and water-oil emulsions (types III, IV-A, and VII) will require determinations of both water extractability and heptane extractability. Low-moisture fats and oils (type V with no free water) require only the heptane extractability. Alcoholic beverages (type VI-A) require only the 8 percent alcohol extractant. Having selected the appropriate extractant or extractants simulating various types of foods and beverages and the time-temperature exaggerations over normal use, follow the applicable extraction procedure. Adapt the procedure, when necessary, for containers having a capacity of

over 1 gallon.

(2) *Selection of coated-container samples.* For consumer-sized containers up to 1 gallon, quadruplicate samples of representative containers (using for each replicate sample the number of containers nearest to an area of 180 square inches) should be selected from the lot to be examined.

(3) *Cleaning procedure preliminary to determining the amount of extractables from coated containers.* Quadruplicate samples of representative containers should be selected from the lot to be examined and must be carefully rinsed to remove extraneous material prior to the actual extraction procedure. Soda fountain pressure-type hot water rinsing equipment, consisting in its simplest form of a1/8-inch-1/4-inch internal diameter metal tube attached to a hot water line and bent so as to direct a stream of water upward, may be used. Be sure hot water has reached a temperature of 190 deg. F-200 deg. F before starting to rinse the container. Invert the container over the top of the fountain and direct a strong stream of hot water against the bottom and all sides for 1 minute, drain, and allow to dry.

(4) *Exposure conditions* --(i) *Water (250 deg. F for 2 hours), simulating high-temperature heat sterilization.* Fill the container within1/4-inch of the top with a measured volume of demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker. Add a small amount of demineralized distilled water to the pressure cooker, but do not allow the water to touch the bottom of the container. Close the cooker securely and start to heat over a suitable burner. When a steady stream of steam emerges from the vent, close the vent and allow the pressure to rise to 15 pounds per square inch (250 deg. F) and continue to maintain this pressure for 2 hours. Slowly release the pressure, open the pressure cooker when the pressure reads zero, and composite the water of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ii) *Water (212 deg. F for 30 minutes), simulating boiling water sterilization.* Fill the container within1/4-inch of the top with a measured volume of boiling, demineralized distilled water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iii) *Water (from boiling to 100 deg. F), simulating hot fill or pasteurization above 150 deg. F.* Fill the container within1/4-inch of

the top with a measured volume of boiling, demineralized distilled water. Insert a thermometer in the water and allow the uncovered container to stand in a room at 70 deg. F-85 deg. F. When the temperature reads 100 deg. F, composite the water from each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(iv) *Water (150deg. for 2 hours), simulating hot fill or pasteurization below 150 deg. F.* Preheat demineralized distilled water to 150 deg. F in a clean Pyrex flask. Fill the container within1/4-inch of the top with a measured volume of the 150 deg. F water and cover with clean aluminum foil. Place the test container in an oven maintained at 150 deg. F. After 2 hours, remove the test container from the oven and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(v) *Water (120 deg. F for 24 hours), simulating room temperature filling and storage.* Preheat demineralized distilled water to 120 deg. F in a clean Pyrex flask. Fill the container within1/4-inch of the top with a measured volume of the 120 deg. F water and cover with clean aluminum foil. Place the test container in an incubator or oven maintained at 120 deg. F. After 24 hours, remove the test container from the incubator and immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vi) *Water (70 deg. F for 48 hours), simulating refrigerated storage.* Bring demineralized distilled water to 70 deg. F in a clean Pyrex flask. Fill the container within1/4-inch of the top with a measured volume of the 70 deg. F water, and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70 deg. F. After 48 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(vii) *Water (70 deg. F for 24 hours), simulating frozen storage.* Bring demineralized distilled water to 70 deg. F in a clean Pyrex flask. Fill the container within1/4-inch of the top with a measured volume of the 70 deg. F water and cover with clean aluminum foil. Place the container in a suitable room maintained at 70 deg. F. After 24 hours, immediately composite the water of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(viii) *Water (212 deg. F for 30 minutes), simulating frozen foods reheated in the container.* Fill the container to within1/4-inch of the top with a measured volume of boiling, demineralized distilled

water. Cover the container with clean aluminum foil and place the container on a rack in a pressure cooker in which a small amount of demineralized distilled water is boiling. Do not close the pressure vent, but operate at atmospheric pressure so that there is a continuous escape of a small amount of steam. Continue to heat for 30 minutes, then remove the test container and composite the contents of each replicate immediately in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(ix) *Heptane (150 deg. F for 2 hours) simulating high-temperature heat sterilization for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 deg. F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 150 deg. F. At the same time preheat a pressure cooker or equivalent to 150 deg. F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within1/4-inch of the top with a measured volume of the 150 deg. F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 150 deg. F incubator. After 2 hours, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(x) *Heptane (120 deg. F for 30 minutes), simulating boiling water sterilization of fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 deg. F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120 deg. F. At the same time, preheat a pressure cooker or equivalent to 120 deg. F in an incubator. This pressure cooker is to serve only as a vented container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within1/4-inch of the top with a measured volume of the 120 deg. F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120 deg. F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xi) *Heptane (120 deg. F for 15 minutes), simulating hot fill or pasteurization above 150 deg. F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 deg. F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 120 deg. F. At the same time, preheat a pressure cooker or equivalent to 120 deg. F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to

minimize the danger of explosion. Fill the test container within1/4-inch of the top with a measured volume of the 120 deg. F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120 deg. F incubator. After 15 minutes, remove the pressure cooker from the incubator, open the assembly, and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xii) *Heptane (100 deg. F for 30 minutes), simulating hot fill or pasteurization below 150 deg. F for fatty foods only.* Preheat redistilled reagent-grade heptane (boiling point 208 deg. F) carefully in a clean Pyrex flask on a water bath or nonsparking hot plate in a well-ventilated hood to 100 deg. F. At the same time, preheat a pressure cooker or equivalent to 100 deg. F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within1/4-inch of the top with a measured volume of the 100 deg. F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 100 deg. F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiii) *Heptane (70 deg. F for 30 minutes), simulating room temperature filling and storage of fatty foods only.* Fill the test container within1/4-inch of the top with a measured volume of the 70 deg. F heptane and cover with clean aluminum foil. Place the test container in a suitable room maintained at 70 deg. F. After 30 minutes, composite the heptane of each replicate in a clean Pyrex flask or beaker. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xiv) *Heptane (120 deg. F for 30 minutes), simulating frozen fatty foods reheated in the container.* Preheat redistilled reagent-grade heptane (boiling point 208 deg. F) carefully in a clean Pyrex flask on a water bath or hot plate in a well-ventilated hood to 120 deg. F. At the same time, preheat a pressure cooker to 120 deg. F in an incubator. This pressure cooker is to serve only as a container for the heptane-containing test package inside the incubator in order to minimize the danger of explosion. Fill the test container within1/4-inch of the top with a measured volume of the 120 deg. F heptane and cover with clean aluminum foil. Place the test container in the preheated pressure cooker and then put the assembly into a 120 deg. F incubator. After 30 minutes, remove the pressure cooker from the incubator, open the assembly and immediately composite the heptane from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xv) *Alcohol--8 percent (150 deg. F for 2 hours), simulating alcoholic beverages hot filled or pasteurized below 150 deg. F.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 150 deg. F in a clean Pyrex flask. Fill the test container with within1/4-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil and place in an oven maintained at 150 deg. F. After 2 hours, remove the container from the oven and immediately composite the alcohol from each replicate in a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvi) *Alcohol--8 percent (120 deg. F for 24 hours), simulating alcoholic beverages room-temperature filled and stored.* Preheat 8 percent (by volume) ethyl alcohol in demineralized distilled water to 120 deg. F in a clean Pyrex flask. Fill the test container within1/4-inch of the top with a measured volume of the 8 percent alcohol, cover the container with clean aluminum foil and place in an oven or incubator maintained at 120 deg. F. After 24 hours, remove the container from the oven or incubator and immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

(xvii) *Alcohol--8 percent (70 deg. F for 48 hours), simulating alcoholic beverages in refrigerated storage.* Bring 8 percent (by volume) ethyl alcohol in demineralized distilled water to 70 deg. F in a clean Pyrex flask. Fill the test container within1/4-inch of the top with a measured volume of the 8 percent alcohol. Cover the container with clean aluminum foil. Place the test container in a suitable room maintained at 70 deg. F. After 48 hours, immediately composite the alcohol from each replicate into a clean Pyrex flask. Proceed with the determination of the amount of extractives by the method described in paragraph (e)(5) of this section.

Note:

The tests specified in paragraph (e)(4) (i) through (xvii) of this section are applicable to flexible packages consisting of coated metal contacting food, in which case the closure end is double-folded and clamped with metal spring clips by which the package can be suspended.

(5) *Determination of amount of extractives* --(i) *Total residues.* Evaporate the food-simulating solvents from paragraph (e)(4) (i) to (xvii), inclusive, of this section to about 100 milliliters in the Pyrex flask and transfer to a clean, tared platinum dish, washing the flask three times with the solvent used in the extraction procedure, and evaporate to a few milliliters on a nonsparking low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at a temperature of 212 deg. F. Cool the platinum dish in a desiccator for 30 minutes and weigh the residue to the nearest 0.1 milligram (e). Calculate the extractives in milligrams per square

inch and in parts per million for the particular size of container being tested and for the specific food-simulating solvent used.

(*a*) *Water and 8-percent alcohol.*

$$\text{Milligrams extractives per square inch} = \frac{e}{s} \quad \textit{Extractives} \text{ residue} = \frac{Ex = (e)(a)(1000)}{(c)(s)}$$

(*b*) *Heptane.*

$$\text{Milligrams extractives per square inch} = \frac{e}{(s)(F)} \quad \textit{Extractives} \text{ residue} = \frac{Ex = (e)(a)(1000)}{(c)(s)(F)}$$

where:

Ex =Extractives residue in ppm for any container size.

e =Milligrams extractives per sample tested.

a =Total coated area, including closure in square inches.

c =Water capacity of container, in grams.

s =Surface of coated area tested, in square inches.

F =Five, the ratio of the amount of extractives removed from a coated container by heptane under exaggerated time-temperature test conditions compared to the amount extracted by a fat or oil from a container tested under exaggerated conditions of thermal sterilization and use.

e' =Chloroform-soluble extractives residue.

ee' =Zinc corrected chloroform-soluble extractive residue.

e' or *ee'* is substituted for *e* in the above equations when necessary.

If when calculated by the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section, the concentration of extractives residue (*Ex*) exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed to paragraph (e)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residue).

(ii) *Chloroform-soluble extractives residue.* Add 50 milliliters of chloroform (freshly distilled reagent grade or a grade having an established consistently low blank) to the dried and weighed residue, (*e*), in the platinum dish, obtained in paragraph (e)(5)(i) of this

section. Warm carefully, and filter through Whatman No. 41 filter paper in a Pyrex funnel, collecting the filtrate in a clean, tared platinum dish. Repeat the chloroform extraction, washing the filter paper with this second portion of chloroform. Add this filtrate to the original filtrate and evaporate the total down to a few milliliters on a low-temperature hotplate. The last few milliliters should be evaporated in an oven maintained at 212 deg. F. Cool the platinum dish in a desiccator for 30 minutes and weigh to the nearest 0.1 milligram to get the chloroform-soluble extractives residue (*e* '). This *e* ' is substituted for *e* in the equations in paragraph (e)(5)(i) (*a*) and (*b*) of this section. If the concentration of extractives (*Ex*) still exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed as follows to correct for zinc extractives ("C" enamels only): Ash the residue in the platinum dish by heating gently over a Meeker-type burner to destroy organic matter and hold at red heat for about 1 minute. Cool in the air for 3 minutes, and place the platinum dish in the desiccator for 30 minutes and weigh to the nearest 0.1 milligram. Analyze this ash for zinc by standard Association of Official Agricultural Chemists methods or equivalent. Calculate the zinc in the ash as zinc oleate, and subtract from the weight of chloroform-soluble extractives residue (*e* ') to obtain the zinc-corrected chloroform-soluble extractives residue (*ee* '). This *ee* ' is substituted for *e* in the formulas in paragraph (e)(5)(i) (*a*) and (*b*) of this section. To comply with the limitations in paragraph (c) of this section, the chloroform-soluble extractives residue (but after correction for the zinc extractives in case of "C" enamels) must not exceed 50 parts per million and must not exceed in milligrams per square inch the limitations for the particular article as prescribed in paragraph (c) of this section.

(f) *Equipment and reagent requirements* --(1) *Equipment.*

Rinsing equipment, soda fountain pressure-type hot water, consisting in simplest form of a1/8-inch-1/4-inch inside diameter metal tube attached to a hot water line delivering 190 deg. F-200 deg. F water and bent so as to direct a stream of water upward.

Pressure cooker, 21-quart capacity with pressure gage, safety release, and removable rack, 12.5 inches inside diameter * 11 inches inside height, 20 pounds per square inch safe operating pressure.

Oven, mechanical convection, range to include 120 deg. F-212 deg. F explosion-proof, inside dimensions (minimum), 19" * 19" * 19", constant temperature to +/-2 deg. F (water bath may be substituted).

Incubator, inside dimensions (minimum) 19" * 19" * 19" for use at 100 deg. F+/-2 deg. F explosion proof (water bath may be substituted).

Constant-temperature room or chamber 70 deg. F+/-2 deg. F inside dimensions 19" * 19" * 19".

Hot plate, nonsparking (explosion proof), top 12" * 20", 2,500 watts, with temperature control.

Platinum dish, 100-milliliter capacity minimum.

All glass, Pyrex or equivalent.

(2) *Reagents.*

Water, all water used in extraction procedure should be freshly demineralized (deionized) distilled water.

Heptane, reagent grade, freshly redistilled before use, using only material boiling at 208 deg. F.

Alcohol, 8 percent (by volume), prepared from undenatured 95 percent ethyl alcohol diluted with demineralized or distilled water.

Chloroform, reagent grade, freshly redistilled before use, or a grade having an established, consistently low blank.

Filter paper, Whatman No. 41 or equivalent.

(g) 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.

(h) Acrylonitrile copolymers identified in this section shall comply with the provisions of 180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977]

Editorial Note:

For Federal Register citations affecting 175.300, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.