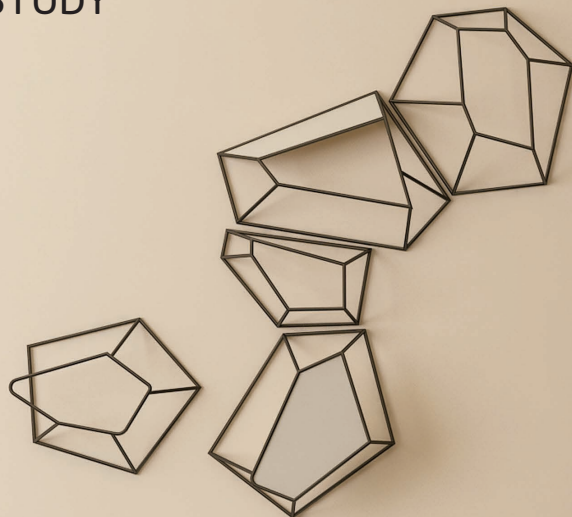


# 《全球合规快讯》

GLOBAL COMPLIANCE EXPRESS

法规更新、召回案例解读

REGULATIONS & LAWS, RECALL CASES STUDY





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PART 1 Wooden furniture& Composite Wood Products 木家具和复合木制品

1 Argentina – Proposed Amendment Technical Regulation for wooden furniture

阿根廷 – 提议木制家具技术法规修正案

The Secretary of Commerce published draft amendment to Resolution 240/2019 (Technical Regulation that establishes the quality and safety requirements for wood-derived furniture). If approved as proposed, it shall enter in force immediately. The major proposed amendments are highlighted below:

阿根廷商务部长发布第 240/2019 号决议（确立木制品质量和安全要求的技术法规）的修正案草案。如果提议案获得批准，则立即生效。提议的主要修订如下：

- 1) 2<sup>nd</sup> Article: replaces Annex I, II and III for Annex *F-2020-XXXXXXXXX-APN-XXXX#MDP*

第二条：替换附录 *F-2020-XXXXXXXXX-APN-XXXX# MDP* 的附件 I、II 和 III

- 2) Tests: includes requirements for evaluation of formaldehyde according to Standards IRAM 9711 "Determination of formaldehyde emission by the desiccator method" and IRAM 9712 "Determination of formaldehyde emission by gas analysis method"

测试：包括根据标准 IRAM 9711“干燥器法测定甲醛释放量”和标准 IRAM 9712“气体分析法测定甲醛释放量”对甲醛的评估要求



3) Other amendments 其他修订

	Res. 240/2019 (in force) 240/2019 号决议（现行）	Draft Amendment (proposed) 提议的修订
Article 4th 第四条	<p>The Enforcement Authority may require national manufacturers and importers to present the documentation provided for in Article 2 of this resolution, which must be submitted through "Plataforma de Trámites a Distancia" ("Remote Procedures Platform") (TAD) approved by Decree No. 1,063 dated October 4, 2016, or the digital system that will replace it in the future.</p> <p>执法机关可以要求国内制造商和进口商提供本决议第 2 条规定的文件，这些文件必须经由 2016 年 10 月 4 日颁布的第 1063 号法令批准的“远程程序平台”（TAD）提交，或通过未来将取代该系统的数字系统提交。</p> <p>In the event that, from the analysis of the requested documentation, a breach of the provisions of this measure arises, the Enforcement Authority will apply the sanctions established in Article 6 of this resolution.</p> <p>如果通过对所要求的文件的分析发现存在违反本措施规定的情况，执法机构将适用本决议第 6 条规定的制裁。</p>	<p>With compliance with the requirements set forth in this resolution, the Dirección Nacional de Reglamentos Técnicos (National Directorate of Technical Regulations), dependent on the Subsecretaría de Políticas para Mercado Interno (Undersecretariat for Internal Market Policies), of the Secretaría de Comercio Interior (Secretariat of Internal Trade) of the Ministerio de Desarrollo Productivo (Ministry of Productive Development), will issue a presentation certificate to be exhibited to the Dirección General de Aduanas (General Directorate of Customs), dependent on the Administración Federal de Ingresos Públicos (Federal Administration of Public Income), an autarkic entity in the field of the Ministerio de Economía (Ministry of Economy), for the purposes of the release to market of the products covered by this regime.</p> <p>根据本决议规定的要求，国家技术法规局将颁发一份介绍证书，用以提供给海关总局，从而保证将本规定所涵盖的产品投放市场。</p>



Annex 附录

<p>Labelling requirements 标签要求</p>	<p>a) Name and/or brand of the manufacturer and/or importer 制造商和/或进口商的名称和/或品牌。</p> <p>b) Country of origin 原产国。</p> <p>c) Mention of the technical standard by which it certifies 认证涉及的技术标准。</p> <p>d) Type of panel (identification code), for example, panel for general use in a dry environment (PS). 板材类型（识别代码），如，一般用于干燥环境中使用的板材 (PS) 。</p> <p>e) Nominal thickness 公称厚度。</p> <p>f) Class according to formaldehyde content 按甲醛含量分类的类别。</p> <p>g) Batch number or date of manufacture 批号或生产日期。</p> <p>h) In the case of certification, Security Seal corresponding to the chosen Certification System, as determined by Resolutions No. 799 dated October 29, 1999 from the former Secretaría de Industria, Comercio y Minería (Secretariat of Industry, Trade and Mining) of the former Ministerio de Economía y Obras y Servicios Públicos (Ministry of Economy and Works and Public Services) and 197 dated December 29, 2004 from the former Secretaría de Coordinación Técnica (Secretariat of</p>	<p>a) Name and/or brand of the manufacturer and/or importer 制造商和/或进口商的名称和/或品牌</p> <p>b) Batch number 批号</p> <p>c) Security Seal corresponding to the chosen Certification System, as determined by Resolutions No. 799 dated October 29, 1999 from the former Secretaría de Industria, Comercio y Minería (Secretariat of Industry, Trade and Mining) of the former Ministerio de Economía y Obras y Servicios Públicos (Ministry of Economy and Works and Public Services) and 197 dated December 29, 2004 from the former Secretaría de Coordinación Técnica (Secretariat of Technical Coordination) of the former Ministerio de Economía y Producción (Ministry of Economy and Production).</p> <p>与所选认证系统相对应的安全印章（来自前经济和工程和公共服务部的前工业、贸易和矿业秘书处的 1999 年 10 月 29 日第 799 号决议和来自前经济和生产部的前技术协调秘书处的 2004 年 2 月 29 日第 197 号决议）。</p> <p>In the lower part, below the cited stamp, the legend "Res. SC N° xx/yyyy" (where "xx" is the number of this resolution and "yyyy" is the year it was issued).</p> <p>在印章下方较低处的图例"Res. SC N° xx /</p>
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	<p>Technical Coordination) of the former Ministerio de Economía y Producción (Ministry of Economy and Production).</p> <p>认证产品的与所选认证系统相对应的安全印章（来自前经济和工程和公共服务部的前工业、贸易和矿业秘书处的 1999 年 10 月 29 日第 799 号决议和来自前经济和生产部的前技术协调秘书处的 2004 年 2 月 29 日第 197 号决议）。</p> <p>In the lower part, below the cited stamp, the legend "Res. SC N° xx/yyyy" (where "xx" is the number of this resolution and "yyyy" is the year it was issued).</p> <p>在印章下方较低处的图例"Res. SC N° xx / yyyy"（其中"xx"为决议的编号，"yyyy"为其发布年份）。</p> <p>All other product information may be included on labels, stamps, tags, stickers, stamps, stamping or the like, provided that this does not cause confusion or may mislead the consumer.</p> <p>所有其他可能包含在标签、印章、吊牌、贴纸、印章、印记等类似标识上的、不会引起混淆或误导消费者的产品信息。</p>	<p>yyyy"（其中"xx"为决议的编号，"yyyy"为其发布年份）。</p> <p>All other product information may be included on labels, stamps, tags, stickers, stamps, stamping or the like, provided that this does not cause confusion or may mislead the consumer.</p> <p>所有其他可能包含在标签、印章、吊牌、贴纸、印章、印记等类似标识上的、不会引起混淆或误导消费者的产品信息。</p>
Item 3 – Procedures 条目 3-程序	<p>Compliance with the requirements established in this resolution will be made effective by preparing an affidavit and subsequently obtaining a product certificate, granted by a Recognized Certification Body, in accordance</p>	<p>Compliance with the requirements established in this resolution will be made effective by preparing an affidavit and subsequently obtaining a product certificate, granted by a Recognized Certification Body, in accordance</p>



<p>with the certification system No. 4 (Test Type), No. 5 (Conformity Mark), or No. 7 (Lot), as established in Resolution No. 197/04 of the former SECRETARIAT OF TECHNICAL COORDINATION of the former MINISTRY OF ECONOMY AND PRODUCTION.</p> <p>符合本决议规定的要求的产品，在准备一份宣誓书后，将获得由认可的认证机构根据认证体系（由前经济和生产部前技术协调秘书处第 197/04 号决议所确定）第 4、第 5 或第 7 部分的规定所颁发的产品证书。</p>	<p>with the certification system No. 5 (Conformity Mark), in accordance with the guidelines established in ISO/IEC 17067.</p> <p>符合本决议规定的要求的产品，在准备一份宣誓书后，将获得由认可的认证机构根据第 5 部分（符合性标志）（符合 ISO/IEC 17067 中制定的指南）的规定所颁发的产品证书。</p>
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## 2 Canada - Approve Formaldehyde Emissions from Composite Wood Products Regulation(SOR/2021-148)

### 加拿大-批准复合木甲醛排放法规(SOR/2021-148)

The Minister of the Environment and The Minister of health approved Formaldehyde Emissions from Composite Wood Products Regulations, which was published in the Canada Gazette, Part II on July 07,2021, it will come into force from Jan 07,2023, Here are the highlights:



2021 年 7 月 7 日，加拿大环境部和卫生部批准了复合木甲醛排放法规，该法规已在《加拿大公报》第二部分公布，将于 2023 年 1 月 7 日起正式生效。以下是法规重点：

#### A. Scope 管控范围

The Regulations shall apply to any composite wood product that contains formaldehyde. Most products imported or sold in Canada will need to comply with the applicable requirements once the Regulations come into force. However, the emission requirements specific to laminated products will not take effect until five years after the Regulations come into force, nor will testing and certification requirements for laminated products. Furthermore, the Regulations would not apply to products manufactured in Canada or imported before the coming-into-force date, so long as records are available to demonstrate the date of manufacture.

该法规适用于任何含甲醛的复合木制品。在加拿大进口或销售的大多数复合木制品，均须符合相应的要求。然而，层压制品的排放要求在法规生效的五年后（2028 年 1 月 7 日）才生效。此外，只要有记录证明，生效日期之前在加拿大制造或进口的产品不受此法规管制。

#### B. Formaldehyde emission limits 甲醛排放限值

The Regulations establish maximum formaldehyde emission levels from composite wood products. These emission limits, expressed as the



concentration of formaldehyde resulting from specific test methods, are the same as those in the U.S.:

该法规规定了复合木制品的最大甲醛排放标准。这些排放限值以特定测试方法（ASTM D6007, ASTM E1333）得出的甲醛浓度来表示，与美国 EPA TSCA Title VI 法规的排放限值相同：

- 0.05 parts per million (ppm) for hardwood plywood;  
硬木胶合板，0.05 ppm
- 0.09 ppm for particleboard;  
刨花板，0.09ppm
- 0.11 ppm for medium-density fibreboard;  
中密度纤维板，0.11ppm
- 0.13 ppm for thin medium-density fibreboard;  
薄中密度纤维板，0.13ppm
- 0.05 ppm for laminated products.  
层压制品，0.05ppm

### C. Labelling and Certification requirement 标签和认证要求

All composite wood products must be labelled prior to being sold in Canada, or the seller must keep a copy of the label and have it available upon request. Composite wood products that already have a bilingual label indicating compliance with the U.S. Rule will be recognized as compliant with Canadian labelling requirements. Composite wood panels and laminated products must also be certified by a third-party certifier



(TPC) prior to import or sale (Composite wood products that have been certified under TSCA Title VI will be accepted as certified under the Regulations).

所有复合木制品在加拿大销售前必须贴上标签，或者销售商必须保留一份标签的副本，并可任何时候提供。已经有双语标签（英语和法语）表明符合美国 TSCA Title VI 法规的复合木制品将被认定为符合加拿大的标签要求。复合木板和层压产品在进口或销售前还必须

经过第三方认证机构（TPC）的认证（备注：已获得 TSCA Title VI 认证的复合木产品将被该法规所接受）。

#### D. Record keeping requirements 记录保存要求

Manufacturers of composite wood panels and laminated products will be expected to keep extensive records of testing, and to make those records available to the Minister of the Environment upon request. Importers and retailers will need to keep statements of certification for their products. Some additional requirements to obtain information from manufacturers exist for importers. In addition, the Regulations will also require all regulated businesses to self-identify by informing the Minister of the Environment of which regulated activity they are involved in and their contact information.

复合木板和层压制品的制造商将被要求保留大量的测试记录，并应环境部要求向其提供这些记录。进口商和零售商将需要保留其产品的认证声明。对于进口商来说，还有一些额外要求。此外，该法规





还将要求所有受监管的企业通过告知环境部所参与的受监管活动和他们的联系信息来进行自我认定。

#### E. Reporting requirements 上报要求

Every person that manufactures, imports, sells or offers for sale a composite wood product that contains formaldehyde must provide the Minister with the following information in writing:

制造、进口、销售或出售含有甲醛的复合木制品的人员必须向环境部提供以下书面信息:

- its name, civic and postal addresses, telephone number and, if any, email address as well as the name of its contact person;  
名称、地址、电话号码、电子邮件以及相关联系人的姓名;
- a statement of whether it manufactures, imports, sells or offers for sale composite wood panels, laminated products, component parts or finished goods, as the case may be.

有关该公司是否制造、进口、出售或提供复合木板、层压产品、部件或成品的声明。



PART 2 Food contact materials 食品接触材料

3 Thailand - Proposed to Amend Ministerial Regulation on PVC, PC, PA, PMMA Plastic Food Contact Article

泰国-提议修订食品接触用 PVC、PC、PA 和 PMMA 塑料制品的部颁法规

The Ministry of Industry has proposed a Ministerial Regulation to mandate the standard TIS 655 Volume 2-2554. This standard shall cover plastic food contact article that are made up of polyvinylchloride, polycarbonate, polyamide, poly (methyl methacrylate).

泰国工业部提议了一项部颁法规以修订强制标准 TIS 655 第 2-2554 卷。该标准适用于由聚氯乙烯、聚碳酸酯、聚酰胺和聚甲基丙烯酸甲酯制成的食品接触用塑料制品。

1) Scope 范围

Plastic container and utensil intended to contact with food. The materials used for the plastic containers must be either one of the following:

与食品接触的塑料容器和器具。用于制备塑料容器的材料必须是以下之一：



Polyvinylchloride 聚氯乙烯	PVC
Polycarbonate 聚碳酸酯	PC
Polyamide 聚酰胺	PA
Poly (methyl methacrylate) 聚甲基丙烯酸甲酯	PMMA

## 2) Food contact articles shall meet the following requirements:

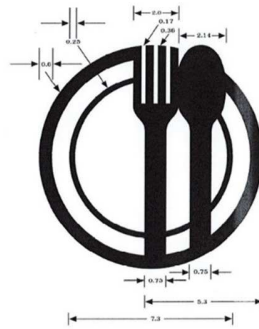
### 食品接触制品需满足以下要求：

- A. Material 材料
- B. Physical characteristics 物理特性
- C. Temperature resistance 耐温性
- D. Odor and taste 气味和味道
- E. Impact resistance 抗冲击性
- F. Safety feature, including: 安全要求，包括：
  - Color 颜色
  - Paint mixed in melted plastic 混合在熔融塑料中的色粉
  - Dissolved substance content 可溶性物质
  - Metal and organic substances 金属和有机物质
- G. Packaging 包装



### 3) Labelling requirements 标签要求

- A. Product name 产品名称
- B. Category 类别
- C. Plastic types and/or symbols according to TIS 1310  
TIS 1310 规定的塑料类型和/或符号
- D. Size in mm or capacity in L  
以毫米 mm 标注的尺寸和以升 L 标注的容量
- E. Quantity (number of article) 数量（物品的数量）
- F. Normal use temperature 使用温度
- G. The word "Single use" if the containers are for single use  
如果为一次性使用产品，标记“一次性使用”字样
- H. Warning statement “ห้ามใช้กับเตาไมโครเวฟ” (Mean: Do not use in a microwave oven)  
警告语“ห้ามใช้กับเตาไมโครเวฟ”（意为：不可用于微波炉）
- I. Warning sign for each article that the contain shall not be placed near flame or contain hot food  
每件物品都需要有的警告标志，该容器不得靠近火焰或盛放热食
- J. For chopping boards, the warning “ไม่เหมาะสำหรับรองสับด้วยมีดขนาดใหญ่” (Mean: Not suitable for chopping with large knives) shall be marked.  
对于砧板，必须加警告语“ไม่เหมาะสำหรับรองสับด้วยมีดขนาดใหญ่”  
（意为：不适合用大的刀切菜）
- K. Symbol to indicate that it is safe to contact with foodstuff without posing any hazard  
表示可以安全接触食品而不造成任何危害的符号



- a.
- L. Date, month, year of making or model code made  
制造日期、月份、年份或型号代码
  - M. Name of manufacturer, factory, or registered trademarks  
制造商、工厂或注册商标的名称。

#### 4 Thailand - Proposed to Amend Ministerial Regulation on ABS, SAN Plastic Food Contact Article

##### 泰国-提议修订食品接触用 ABS 和 SAN 塑料制品的部颁法规

The Ministry of Industry has proposed a Ministerial Regulation to mandate the standard TIS 655 Volume 3-2554. This standard shall cover plastic food contact article that are made up of acrylonitrile-butadiene-styrene (ABS) and styrene-acrylonitrile (SAN).





泰国工业部提议了一项部颁法规以修订强制标准 TIS 655 第 3-2554 卷。该标准适用于由丙烯腈-丁二烯-苯乙烯 (ABS) 和苯乙烯-丙烯腈 (SAN) 制成的食品接触用塑料制品。

### 1) Scope 范围

Plastic container and utensil intended to contact with food. The materials used for the plastic containers must be acrylonitrile-butadiene-styrene (ABS) and styrene-acrylonitrile (SAN).

与食品接触的塑料容器和器具。用于制备塑料容器的材料必须是丙烯腈-丁二烯-苯乙烯 (ABS) 和苯乙烯-丙烯腈 (SAN)。

### 2) Food contact articles shall meet the following requirements:

#### 食品接触制品需满足以下要求：

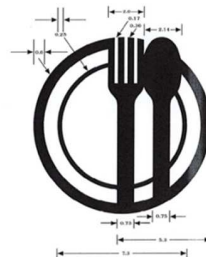
- A. Material 材料
- B. Physical characteristics 物理特性
- C. Temperature resistance 耐温性
- D. Odor and taste 气味和味道
- E. Impact resistance 抗冲击性
- F. Safety feature, including: 安全要求，包括：
  - Color 颜色
  - Paint mixed in melted plastic 混合在熔融塑料中的色粉
  - Lacquer 清漆
  - Dissolved substance content 可溶性物质
  - Metal and plastic content 金属和有机物质



G. Packaging 包装

3) Labelling requirements 标签要求

- A. Product name 产品名称
- B. Plastic types and/or symbols according to TIS 1310  
TIS 1310 规定的塑料类型和/或符号
- C. Size in mm or capacity in L  
以毫米 mm 标注的尺寸和以升 L 标注的容量
- D. Quantity (number of article) 数量（物品的数量）
- E. Warning to state that the article shall not place near flames, do not use in a microwave, do not use with hot food.  
说明该容器不得靠近火焰、不可用于微波或盛放热食的警告标志
- F. Symbol to indicate that it is safe to contact with foodstuff without posing any hazard  
表示可以安全接触食品而不造成任何危害的符号





G. Date, month, year of making or model code made

制造日期、月份、年份或型号代码

H. Name of manufacturer, factory, or registered trademarks

制造商、工厂或注册商标的名称。

## 5 Thailand - Proposed to Amend Ministerial Regulation on PE, PP, PS, PET, PVAL, PMP Plastic Food Contact Article

### 泰国-提议修订食品接触用 PE、PP、PS、PET、PVAL 和 PMP 塑料制品的部颁法规

The Ministry of Industry has proposed a Ministerial Regulation to mandate the standard TIS 655 Volume 1-2553. This standard shall cover plastic food contact article that are made up of polyethylene, polypropylene, polystyrene, polyethylene terephthalate, poly(vinyl alcohol), poly(methyl pentene).

泰国工业部提议了一项部颁法规以修订强制标准 TIS 655 第 1-2553 卷。该标准适用于由聚乙烯、聚丙烯、聚苯乙烯、聚对苯二甲酸乙二醇酯、聚乙烯醇和聚甲基戊烯制成的食品接触用塑料制品。

#### 1) Scope 范围

Plastic container and utensil intended to contact with food. The materials used for the plastic containers must be either one of the following:



与食品接触的塑料容器和器具。用于制备塑料容器的材料必须是以下之一：

Polyethylene 聚乙烯	PE
Polypropylene 聚丙烯	PP
Polystyrene 聚苯乙烯	PS
Polyethylene terephthalate 聚对苯二甲酸乙二醇酯	PET
Poly (vinyl alcohol) 聚乙烯醇	PVAL
Poly (methyl pentene) 聚甲基戊烯	PMP

2) Food contact articles shall meet the following requirements:

食品接触制品需满足以下要求：

- A. Material 材料
- B. Physical characteristics 物理特性
- C. Temperature resistance 耐高温性
- D. Odor and taste 气味和味道
- E. Impact resistance 抗冲击性



F. Safety feature, including: 安全要求, 包括:

- Color 颜色
- Paint mixed in melted plastic 混合在熔融塑料中的色粉
- Dissolved substance content 可溶性物质
- Metal and organic substances 金属和有机物质

G. Packaging 包装

### 3) Labelling requirements 标签要求

A. Product name 产品名称

B. Category 类别

C. Plastic types and/or symbols according to TIS 1310  
TIS 1310 规定的塑料类型和/或符号

D. Size in mm or capacity in L  
以毫米 mm 标注的尺寸和以升 L 标注的容量

E. Quantity (number of article)  
数量 (物品的数量)

F. Normal use temperature 使用温度

G. The word "Single use" if the containers are for single use  
如果为一次性使用产品, 标记"一次性使用"字样

H. Warning statement "ห้ามใช้กับเตาไมโครเวฟ" (Mean: Do not use in  
a microwave oven)



警告语“ห้ามใช้กับเตาไมโครเวฟ” (意为：不可用于微波炉)

- I. Warning sign for each article that the contain shall not be placed near flame or contain hot food

每件物品都需要有的警告标志，该容器不得靠近火焰或盛放热食

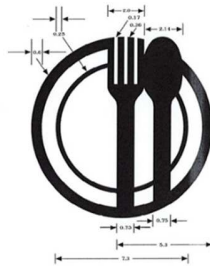
- J. For chopping boards, the warning

“ไม่เหมาะสำหรับรองสับด้วยมีดขนาดใหญ่” (Mean: Not suitable for chopping with large knives) shall be marked.

对于砧板，必须加警告语“ไม่เหมาะสำหรับ รอง สับ ด้วย มหตเม็ตไมต์”  
(意为：不适合用大的刀切菜)

- K. Symbol to indicate that it is safe to contact with foodstuff without posing any hazard

表示可以安全接触食品而不造成任何危害的符号



- L. Date, month, year of making or model code made

制造日期、月份、年份或型号代码

- M. Name of manufacturer, factory, or registered trademarks

制造商、工厂或注册商标的名称。



## 6 China - Proposed New Substances related to Food Contact Materials And Articles

### 中国 – 提议与食品接触材料及制品有关的新物质

The China National Center for Food Safety Risk Assessment (CFSA) has proposed 7 kinds of substances related to food contact materials and articles. Here are the highlights:

中国国家食品安全风险评估中心（CFSA）提议 7 种与食品接触材料及制品有关的新物质。要点如下：

#### 1) New food contact material and article 食品接触材料新品种

Items 项目	CAS No.	Scope 范围	Maximum amount to be used 最大使 用量	Specific Migration Limit 特定迁移限制(SML)	Maximum Residue 最大残留量 (QM)	Note 备注
Silicon dioxide coatings made from the monomers hexamethyldisiloxane and hexamethyldisilazane  以六甲基二硅氧烷 和六甲基二硅氮烷 为原料的氧化硅涂 层	-	Polyethylene terephthalate (PET) coating  聚对苯二甲 酸乙二醇酯 (PET) 涂层	-	0.05 (as hexamethyldisiloxane)  0.05（六甲基二硅氧 烷）	-	PET plastic materials and articles with this coating shall be used for room temperature filling and long-term storage at room temperature (including hot filling and pasteurization at temperature $\leq 70^{\circ}\text{C}$ , $\leq 2$ hours, or $\leq 100^{\circ}\text{C}$ , $\leq 15$ min), shall not be used for irradiated food, not be used in contact with infant food and breast milk  涂覆了该涂层的 PET 塑



						料材料及制品用于室温灌装并在室温下长期贮存（包括 $T \leq 70^{\circ}\text{C}$ , $t \leq 2\text{h}$ 或 $T \leq 100^{\circ}\text{C}$ , $t \leq 15\text{min}$ 条件下的热灌装及巴氏消毒），不得用于辐照食品，不得用于接触婴幼儿食品及母乳
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## 2) New additive of food contact material and article

## 食品接触材料及制品用添加剂新品种

Items 项目	CAS No.	Scope 范围	Maximum amount to be used 最大使用 量	Specific Migration Limit 特定迁移限 制(SML)	Maximum Residue 最大残留量 (QM)	Note 备注
2-Propenoic acid, polymer with 2,5-furandione and 2-propenamide, sodium salt  2-丙烯酸与2,5-呋喃二酮和2-丙烯酰胺聚合物的钠盐	1630821-33-8	Paper and cardboard 纸和纸板	0.041% (as dry weight) 0.041 (以干重计)	-	-ND (Acrylamide, DL=0.01mg/kg) ND (丙烯酰胺, DL=0.01mg/kg) - 6 (as acrylic acid) 6 (以丙烯酸计) -30 (as maleic acid) 30 (以马来酸计)	-

## 3) Expansion of the scope of additive used in food contact material and article

## 扩大范围的食物接触材料及制品中使用的添加剂

Items 项目	CAS No.	Scope 范围	Maximum amount to be used	Specific Migration Limit	Maximum Residue 最大残留量	Note 备注
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			最大使用 量	特定迁移限制 (SML)	(QM)	
Maltodextrin 麦芽糊精	9050-36-6	Adhesive 粘合剂	Use as needed 按生产需 要适量使 用	-	-	-
C.I. pigment blue 15 C.I.颜 料蓝 15	147-14-8	Plastic: Polylactic acid (PLA) 塑料: 聚 乳酸 (PLA)	0.7 %	-	-	<p>PLA plastic materials and articles added with this substance shall not be used for more than 1h; this substance shall meet the requirements for colorant purity in Appendix A of GB 9685-2016</p> <p>添加了该物质的 PLA 塑料材料及制品使用时间不得超过 1h; 该物质应符合 GB 9685-2016 附录 A 对着色剂纯度的要求</p>
C.I. pigment red 254 C.I.颜 料红 254	84632-65-5	Plastic: Polylactic acid (PLA) 塑料: 聚 乳酸 (PLA)	1.4 %	-	-	<p>PLA plastic materials and articles added with this substance shall not be used for more than 1h; this substance shall meet the requirements for colorant purity in Appendix A of GB 9685-2016</p> <p>添加了该物质的 PLA 塑料材料及制品使用时间不得超过 1h; 该物质应符</p>



						合 GB 9685-2016 附录 A 对着色剂纯度的要求
Carbon black 炭黑	1333-86-4	Plastic: Polylactic acid (PLA) 塑料: 聚乳酸 (PLA)	1.5 %	-	-	<p>PLA plastic materials and articles added with this substance shall not be used for more than 1h; this substance shall meet the requirements for colorant purity in Appendix A of GB 9685-2016</p> <p>添加了该物质的 PLA 塑料材料及制品使用时间不得超过 1h; 该物质应符合 GB 9685-2016 附录 A 对着色剂纯度的要求</p>
C.I. pigment yellow 180 C.I. 颜料黄 180	77804-81-0	Plastic: Polylactic acid (PLA) 塑料: 聚乳酸 (PLA)	0.5 %	-	-	<p>PLA plastic materials and articles added with this substance shall not be used for more than 1h; this substance shall meet the requirements for colorant purity in Appendix A of GB 9685-2016</p> <p>添加了该物质的 PLA 塑料材料及制品使用时间不得超过 1h; 该物质应符合 GB 9685-2016 附录 A 对着色剂纯度的要求</p>





**Note 备注:**

1. ND: Not detected 未检出;
2. DL: Detection limit 检出限;
3. GB 9685-2016 National Food Safety Standard: Standard for the Use of Additives in Food Contact Materials and Articles 国家食品安全标准：食品接触材料及制品中添加剂使用标准

**7 Mercosur – Approved amendments on provisions for metallic packaging, linings, utensils, lids and equipment that are in contact with foodstuffs**

**南方共同市场 -批准关于食品接触用金属包装、衬里、器具、盖子和设备规定的修正案**

MERCOSUR has published Resolution no. 16/2020 for amendments on Technical Regulation on provisions for metallic packaging, coating, utensils, lids and equipment that are in contact with foodstuffs (GMC Res. No. 46/2006). States Parties have up to June 15<sup>th</sup>, 2021 for incorporation. The main topics are highlighted below:

南方共同市场发布第 16/2020 号决议，修订关于食品接触用金属包装、涂层、器具、盖子和设备的技术法规（GMC 决议第 46/2006 号）。南方共同市场成员应在 2021 年 6 月 15 日之前将该技术法规的修订纳入本国法规。主要的修订内容如下：

- Item 2.5: changes in side seam packaging techniques  
条目 2.5 侧缝包装技术的变化



- item 2.6: includes information that sealing compounds must follow requirements from item 3.4  
 条目 2.6 密封用化合物必须符合条目 3.4 要求
- Reallocate the table in item 3.1.9.2, which becomes part of item 3.1.1  
 调整条目 3.1.9.2 中的表格，该表格成为条目 3.1.1 的一部分

Item 条目	GMC Resolution no. 46/06 GMC 决议第 46/06 号	GMC Resolution no. 16/20 GMC 决议第 16/20 号
Item 3.1.6	3.1.6 Copper, brass or bronze fully coated with a coating of technically pure gold, silver, nickel or tin. 3.1.6 被工业级的金、银、镍或锡的涂层完全覆盖的铜、黄铜或青铜。	3.1.6 Copper, brass or bronze fully coated with a coating of technically pure gold, silver, nickel or tin. The use of uncoated copper equipment is allowed for the preparation of private foods at an industrial and/or artisanal level at the discretion of the competent health authority whenever its technological function of use is demonstrated 3.1.6 被工业级的金、银、镍或锡的涂层完全覆盖的铜、黄铜或青铜。只要能证明其技术功能，主管卫生当局可酌情决定在工业和/或手工水平上使用无涂层铜设备来制备非公众食用的食品。
Item 3.1.9	3.1.9 Tinplate 马口铁: 3.1.9.1. tin coated tinplate, in the amount necessary to fulfill the technological function. 对于镀锡马口铁，其含量是满足技术功能必需的。 3.1.9.2. tinplate internally, totally or partially	3.1.9. Tinplate 马口铁: 3.1.9.1. Tinplate without polymer coating. 无聚合物涂层的马口铁。 3.1.9.2. Tinplate with internally, totally or partially polymeric coating.



	<p>varnished with polymeric materials. The amount of tin in the tinplate will be that necessary to fulfill the technological function.</p> <p>马口铁内部、全部或部分涂有聚合物材料。马口铁中的锡含量是实现技术功能所必需的。</p>	<p>马口铁内部、全部或部分涂有聚合物材料。</p> <p>In both cases, the amount of tin in the tinplate will be that necessary to fulfill the technological function.</p> <p>在这两种情况下，马口铁中的锡含量是实现技术功能所必需的。</p>
Item 3.1.10	<p>3.1.10 Contaminant metals must not migrate in quantities greater than the limits established in the corresponding MERCOSUR Resolution on contaminants in food.</p> <p>污染物金属的迁移量不得超过相应的南方共同市场决议中关于食品中污染物的规定。</p>	<p>Move item 3.1.10 to 2.9, with the following wording: 将条款 3.1.10 移至 2.9，并使用以下描述：</p> <p>“2.9 Contaminant metals must not migrate in quantities exceeding the limits established in the MERCOSUR Technical Regulation on inorganic contaminants in food or in specific technical regulations.”</p> <p>“2.9 污染物金属的迁移量不得超过 MERCOSUR 技术法规对食品中无机污染物或特定技术法规所规定的限量。”</p>
Item 3.4	<p>3.4. Sealants 密封剂</p> <p>Products included in the positive lists for elastomeric packaging and equipment and their modifications may be used with their restrictions of use, composition and specific migration limits of the corresponding MERCOSUR Resolution.</p> <p>包含在弹性包装和设备的正面清单中的产品及其改进产品可以在其采用相应的使用限制、成分和相应 MERCOSUR 决议的特定迁移限量的情况下使用。</p>	<p>3.4. Sealants 密封剂</p> <p>Products included in the positive lists for elastomeric, plastics and their combinations packaging and equipment may be used with their restrictions of use, composition and specific migration limits of the corresponding MERCOSUR Technical Regulations.</p> <p>包含在弹性体、塑料及其组合包装和设备的正面清单中的产品可以采用其使用限制、成分和相应 MERCOSUR 技术法规的特定迁移限量。</p>
Item 3.5	<p>3.5. Manufacturing adjuvants 生产助剂</p> <p>Surface lubricants: are used to facilitate the</p>	<p>3.5. Surface lubricants (Manufacturing adjuvants): Used in the metal sheet production process to facilitate material sliding, minimizing abrasion and</p>



	<p>embedding, drawing, stamping or molding of metallic objects from stored rolls or sheets, or to wind laminates or store metallic sheets.</p> <p>表面润滑剂：用于促进金属物体从储存的卷或片材中嵌入、拉伸、冲压或成型，或用于缠绕层压板或储存金属片材。</p>	<p>scratches, and/or to facilitate the embedding, stretching, stamping or molding of metal packaging components from the sheets.”</p> <p>表面润滑剂（生产助剂）： 在金属板生产过程中使用，以促进材料滑动，最大限度地减少磨损和划痕，和/或促进金属包装部件的嵌入、拉伸、冲压或成型。</p>
Item 3.5.1	<p>3.5.1. The use of food raw materials is allowed, including additives that correspond to the food that will be packaged or that will be in contact with the object, complying with the specifications established for their use in food. The amount of food raw material or additive present in the food, added to that which migrates from the metallic object, should not exceed the limits established for each food or alter its authenticity.</p> <p>允许使用食品原材料，包括与将要包装的食品或与物体接触的食品相对应的添加剂，如果这些食品原材料和添加剂符合为其在食品中的使用制定的规范。添加到从金属物体迁移的食品原料或食品中添加剂的量，不应超过为每种食品制定的限制或改变食物特性。</p>	<p>3.5.1. The use of food ingredients is allowed, including authorized additives for the food that will be packaged or that will be in contact with the object, whenever:</p> <p>在以下情况下，允许使用食品成分，包括用于将要包装的或将与物体接触的食品的授权添加剂：</p> <p>a) The restrictions established for its use in food are complied with; and 遵守为其在食品中的使用制定的限制；和</p> <p>b) The amount of additive present in the food added to that which may eventually migrate from the packaging does not exceed the limits established for each food. 添加到最终可能从包装中迁移的食品中添加剂的量不超过为每种食品制定的限制。</p>
Item 3.5.3	<p>Polyethoxylated tallow amine (5 mols) 聚乙氧基化牛油胺（5 摩尔）</p>	<p>Polyethoxylated tallow amine (5 mol/L) 聚乙氧基化牛油胺（5 摩尔/升）</p>
Item 3.7	<p>3.7. The substances contained in these lists and their migration limits may be modified when subsequent technical or scientific knowledge indicate any risk to</p>	<p>“3.7. Inclusion and exclusion criteria for substances on the positive list. “3.7. 肯定清单上物质的纳入和剔除标准。</p>



	<p>public health, or to allow the inclusion of new substances, following the criteria of the "MERCOSUR Technical Regulation on general criteria for updating positive lists of packaging and equipment components in contact with food".</p> <p>当之后的技术或科学知识表明对公众健康有任何风险，或允许包含新物质时，与食品接触的包装和设备部件清单中包含的物质及其迁移限制可能会根据“南方共同市场技术法规关于更新阳性的一般标准的一般标准”的标准进行修改。</p>	<p>3.7.1. The list of substances can be modified:</p> <p>3.7.1. 可以修改物质清单：</p> <p>a) For the inclusion of new components, when it is demonstrated that they do not represent a significant risk to human health and the technological need for their use is justified.</p> <p>当证明新物质不会对人类健康构成重大风险并且对其使用的技术需求是合理的情况下，纳入新物质。</p> <p>b) To modify the restrictions of components, when new technical-scientific knowledge justifies it.</p> <p>当新的技术科学知识证明其合理时，修改相关物质的限制。</p> <p>c) To exclude components, when new technical-scientific knowledge indicates a significant risk to human health."</p> <p>当新的技术科学知识表明对人类健康有重大风险时，剔除该物质。”</p>
Item 4.1	<p>4.1. Metal lids, packaging, utensils and equipment, whose surfaces are in contact with food, fully or partially coated with polymeric varnishes or enamels, vitrified or on porcelain, must be subjected to the global migration, specific migration and composition limit tests described in the corresponding MERCOSUR Resolutions.</p> <p>与食品接触的金属盖子、包装、器具和设备，其表面完全或部分涂有聚合物清漆或搪瓷、玻璃化或在瓷器上时，必须符合南方共同市场决议中规定的相应的全迁移限值、特定迁移限值以及成分限制。</p> <p>4.1.1. The total or global migration limits, as</p>	<p>"4.1. Metallic covers, packaging, utensils and equipment, whose surfaces are in contact with food, totally or partially coated with polymeric coatings, varnishes or enamels, with glass or with tableware, must be submitted to total migration, specific migration and limit tests of composition described in the corresponding MERCOSUR Technical Regulations</p> <p>“4.1. 与食品接触的金属盖、包装、器具和设备，其表面全部或部分涂有聚合物涂层、清漆或搪瓷，玻璃或餐具，必须符合南方共同市场决议中规定的相应的全迁移限值、特定迁移限值以及成分限制。</p>



<p>established in the MERCOSUR Resolutions “General Criteria for Food Packaging and Equipment in Contact with Food” and “Glass and Ceramic Packaging and Equipment intended to come into Contact with Food”, are:</p> <p>“与食品接触的食品包装和设备的一般标准”和“拟与食品接触的玻璃和陶瓷包装和设备”的 MERCOSUR 决议中规定的全迁移限制是：</p> <p>-50 mg/kg of simulant, in the case of packaging and equipment with a capacity greater than or equal to 250 ml; in the case of packaging and equipment where it is not possible to estimate the surface area in contact; and in the case of closing elements or small area objects.</p> <p>-50 mg/kg (模拟物)，对于容量大于或等于 250 ml 的包装和设备；对于无法估计接触表面积的包装和设备；对于密闭部件或表面积小的物品。</p> <p>-8 mg/dm<sup>2</sup> of package surface area; in the case of packaging and equipment with a capacity of less than 250 ml; and in the case of generic material.</p> <p>-8 mg/dm<sup>2</sup> （包装物的表面积）；对于容量小于 250 毫升的包装和设备；在通常情况下。</p> <p>They will be carried out on the finished product, applying the methodology indicated in the corresponding MERCOSUR Resolutions.</p> <p>测试将在成品上进行，采用相应的南方共同市场决议中规定的方法。</p> <p>Specimens of the metallic substrate to which it is intended, prepared under the same conditions as the object to be tested, may be used when duly justified,</p>	<p>4.1.1 The total and specific migration tests for the coated materials will be carried out on the finished product.</p> <p>涂层材料的全迁移测试和特定迁移测试将在成品上进行。</p> <p>4.1.2 When duly justified, the total and specific migration tests may be carried out using specimens of the metallic substrate for which it is intended, prepared under the same conditions as the material under analysis. This circumstance must be included in the analysis protocol.</p> <p>当有充分的理由时，可以使用在与被分析材料相同的条件下制备的金属基材样品进行全迁移和特定迁移试验。这种情况必须包含在测试协议中。</p> <p>4.1.3. When duly justified, other materials such as ground glass or stainless steel may be used, in place of the metallic substrate for which it is intended. In this case, the coating must be prepared under the same conditions of use. This circumstance must be included in the analysis protocol.</p> <p>如果有充分的理由，可以使用其他材料，如磨砂玻璃或不锈钢，代替预期的金属基材。在这种情况下，涂层必须在相同的使用条件下制备。这种情况必须包含在测试协议中。</p> <p>4.1.4. The total migration limits are those established in the specific MERCOSUR Technical Regulation that corresponds to the type of coating used.</p> <p>全迁移限量由特定的 MERCOSUR 技术法规中所确定的，与所使用的涂层类型相对应。</p> <p>4.1.5. Correction for metal migration:</p> <p>金属迁移校正：</p>
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<p>and such circumstance must be included in the analysis protocol.</p> <p>在与被测物体相同的条件下制备的预期金属基材样品，如果有正当理由，可以用于测试。且必须包括在测试协议中。</p> <p>4.1.2. Analytical tolerances</p> <p>Analytical tolerances are: 5 mg/kg or 0.8 mg/dm<sup>2</sup> according to the form of expression of the results.</p> <p><b>分析公差</b></p> <p>分析公差为：5 mg/kg 或 0.8 mg/dm<sup>2</sup> (根据结果的表达形式)。</p> <p>4.1.3. Correction by migration of metals In packages with partial polymeric coating, when the total migration is greater than the established limit, an extraction with chloroform must be carried out for correction by migration of metals, described below</p> <p><b>金属迁移的校正</b></p> <p>在具有部分聚合物涂层的包装中，当全迁移量大于既定限值时，必须使用氯仿进行萃取以校正金属迁移，如下所述</p> <p>4.1.3.1 Add 50 ml of chloroform to the residue from the total migration test and heat in a water bath to dissolve it completely. Cool down. Filter through quantitative filter paper to a tared capsule, evaporating completely. Dry in an oven and weigh, repeating the procedure until constant mass. At the same time, carry out a blank test to obtain the corrected residue mass (R').</p> <p>向全迁移试验残渣中加入 50ml 氯仿，水浴加热使其完全溶解。冷却。通过定量滤纸过滤至去皮的小容器中后蒸发至溶剂完全去除。在烘箱中干燥并</p>	<p>In packages with polymeric coating, when the total migration is greater than the established limit, an extraction with chloroform must be carried out for correction by migration of metals, described below:</p> <p>在带有聚合物涂层的包装中，当总迁移量大于既定限值时，必须采用氯仿萃取用于校正金属迁移，如下所述：</p> <p>4.1.5.1 Add 50 ml of chloroform to the residue from the total migration test and heat in a water bath to dissolve it completely. Cool it down. Filter it through quantitative filter paper to a tared capsule, evaporating completely. Dry in an oven and weigh, repeating the procedure until constant mass. This procedure can be repeated several times until the metallic residue is eliminated.</p> <p>向全迁移试验的残渣中加入 50ml 氯仿，水浴加热使其完全溶解。冷却后采用定量滤纸将其过滤到去皮的容器中蒸发至溶剂完全去除。在烘箱中干燥并称重，重复该过程直至质量恒定。这个过程可以重复几次，直到金属残留物被除去。</p> <p>At the same time, carry out a blank test to obtain the corrected residue mass (R').</p> <p>同时进行空白试验，得到修正后的残留质量 (R') 。</p> <p>4.1.5.2. Expression of results:</p> <p><b>结果的表达：</b></p> <p>a) When the migration test is carried out with specimens, the contact area/food mass ratio must be corrected, as established in the MERCOSUR Technical</p>
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<p>称重，重复该过程直至质量恒定。同时进行空白试验，得到修正后的残留质量（R'）。</p> <p>4.1.3.2. Expression of results:</p> <p>结果的表达：</p> <ul style="list-style-type: none"> <li>When the migration test is performed with a generic metallic material, the following formula must be used:</li> </ul> <p>当使用通用的金属材料进行迁移测试时，必须使用以下公式：</p> $Q = R'/A \times S/V$ <p>where:</p> <p>Q: total migration, in mg/kg</p> <p>总迁移量，mg/kg</p> <p>R': corrected residue mass, in mg</p> <p>修正后的残留质量，单位为 mg</p> <p>A: total area of the sample in contact with the simulant, in dm<sup>2</sup></p> <p>样品与模拟物接触的总面积，单位为 dm<sup>2</sup></p> <p>S/V water mass/area ratio corresponding to the actual contact volume between the material and the food, in dm<sup>2</sup>/kg of water.</p> <p>S/V 水质量/面积比对应于材料和食物之间的实际接触体积，单位为平方分米/每千克的水。</p> <ul style="list-style-type: none"> <li>When the migration test is carried out with the final packaging or with lids, then A = S and the formula reduces to:</li> </ul> <p>当迁移测试是用最终包装或盖子进行时，则 A = S，公式简化为：</p> $Q = R'/V$	<p>Regulation on General Provisions for Plastic Packaging and Equipment in Contact with Food, and use the following formula:</p> <p>当对样品进行迁移测试时，必须按照 MERCOSUR 技术法规关于与食品接触的塑料包装和设备的一般规定来修正接触面积/食品质量比，并使用以下公式：</p> $Q = R'/A \times S/V$ <p>where:</p> <p>Q: total migration, in mg/kg</p> <p>总迁移量，mg/kg</p> <p>R': corrected residue mass, in mg</p> <p>修正后的残留质量，单位为 mg</p> <p>A: total area of the sample in contact with the simulant, in dm<sup>2</sup></p> <p>样品与模拟物接触的总面积，单位为 dm<sup>2</sup></p> <p>S/V: contact area/food mass ratio.</p> <p>接触面积/食物质量比。</p> <p>When the migration test is carried out with the final packaging or with lids, then A=S, and the result must be expressed in accordance with the provisions of the MERCOSUR Technical Regulation on General Provisions for Plastic Packaging and Equipment in Contact with Food.</p> <p>当迁移测试是用最终包装或带盖进行时，则 A=S，结果必须按照 MERCOSUR 技术法规《与食品接触的塑料包装和设备的一般规定》的规定表示。</p> <p>To express the result in mg/kg, the formula reduces</p>
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<p>where:</p> <p>Q: total migration, in mg/kg 总迁移量, mg/kg</p> <p>R': corrected residue mass, in mg 修正后的残留质量, 单位为 mg</p> <p>V: mass of water corresponding to the volume of the package, in kg. 与包装材料体积相对应的水质量, 单位为 kg。</p> <p>• Migration can also be expressed in mg/dm<sup>2</sup>, using the following formula: 迁移也可以用 mg/dm<sup>2</sup> 表示, 使用以下公式:</p> <p><math>Q' = R'/A</math> where: Q: total migration, in mg/kg 总迁移量, mg/kg</p> <p>R': corrected residue mass, in mg 修正后的残留质量, 单位为 mg</p> <p>A: total area of the sample in contact with the simulant, in dm<sup>2</sup> 样品与模拟物接触的总面积, 单位为 dm<sup>2</sup></p> <p>4.1.4. Zinc-corrected chloroform soluble residue: 锌-校正氯仿可溶性残留物:</p> <p>For varnishes containing zinc oxide, if the total migration exceeds the established limits, proceed with the determination of the residue soluble in chloroform corrected for zinc, as described below: 对于含有氧化锌的清漆, 如果总迁移量超过既定限</p>	<p>to:</p> <p>为了以 mg/kg 表示结果, 公式简化为:</p> <p><math>Q = R'/V</math> where: Q: total migration, in mg/kg 总迁移量, mg/kg</p> <p>R': corrected residue mass, in mg 修正后的残留质量, 单位为 mg</p> <p>V: mass of water corresponding to the volume of the package, in kg. 与包装材料体积相对应的水质量, 单位为 kg。</p> <p>To express the result in mg/dm<sup>2</sup>, the formula is reduced to: 为了以 mg/dm<sup>2</sup> 表示结果, 公式简化为:</p> <p><math>Q' = R'/A</math> where: Q: total migration, in mg/kg 总迁移量, mg/kg</p> <p>R': corrected residue mass, in mg 修正后的残留质量, 单位为 mg</p> <p>A: total area of the sample in contact with the simulant, in dm<sup>2</sup> 样品与模拟物接触的总面积, 单位为 dm<sup>2</sup></p>
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	<p>值，则继续测定经锌校正的氯仿中可溶残留物，如下所述：</p> <p>4.1.4.1. Calcinate the residue obtained in a platinum capsule by heating in a Meker-type blowtorch or muffle at an equivalent temperature, to destroy the organic material, leaving it to redden for approximately one minute. Cool in air for 3 minutes and then in a desiccator for 30 minutes. Weigh accurately to 0.1 mg. This ash is analyzed for the determination of zinc according to A.O.A.C. or other equivalent method.</p> <p>通过在 Meker 型喷灯或马弗炉中在相同温度下加热来煅烧在铂坩锅中获得的残留物，以破坏有机材料，使其变红约一分钟。在空气中冷却 3 分钟，然后在干燥器中冷却 30 分钟。准确称重至 0.1 mg。根据 A.O.A.C. 方法分析该灰分以测定锌。或采用其他等效方法。</p>	
Item 4.2	<p>4.2. The composition and specific migration limits of polymeric coatings are established in the lists of the corresponding Resolutions in each case and their modifications.</p> <p>聚合物涂层的成分和特定迁移限值在各种情况下的相应决议及其修改案的列表中确定。</p> <p>It will be used as an analysis methodology for CL and SML: "Material and articles in contact with foodstuffs - polymeric coating on metals substrates- ide to selection of conditions and test methods for overall ingration. DD CENT-TS 14235: 2002. BSI-British Standards."</p> <p>以下方法将用作 CL 和 SML 的分析方法：“与食品接触的材料和制品 - 金属基材上的聚合物涂层 - 整</p>	<p>4.2. The composition and specific migration limits of polymeric coatings are those established in the lists of the corresponding MERCOSUR Technical Regulations and their modifications."</p> <p>聚合物涂层的成分和特定迁移限量是在相应的 MERCOSUR 技术法规及其修改案的列表中确定的。</p>



	体浸泡条件和测试方法的选择。DD CENT-TS 14235: 2002。BSI-英国标准。”	
Item 4.4	<p>4.4. Determination of the specific migration of metals in tinplate packaging</p> <p>马口铁包装中金属特定迁移量的测定</p> <p>4.4.1. Simulators and sample preparation. To carry out the specific migration tests for metals, the foods are classified and the respective simulants fixed as follows:</p> <p>模拟物和样品制备</p> <p>为实施金属的特定迁移测试，将食品分类并确定各自的模拟物如下：</p> <p>Type A 类型 A</p> <p>Acidic and non-acidic aqueous foods, sterilized in the package by heat, which may contain salt and/or sugar and include oil/water emulsions, or low in fat: These products must be tested with an aqueous solution containing 3% chloride of sodium, 10% of sucrose and 1% of tartaric acid, with which the package will be filled. Keep the package hermetically closed, containing the solution in a water bath for 2 hours at 100°C or in an autoclave for 30 minutes at 120°C.</p> <p>酸性和非酸性水性食品，在包装中加热灭菌，可能含有盐和/或糖，包括油/水乳液或低脂肪：这些产品必须用含有 3% 氯化钠的水溶液、10% 的蔗糖和 1% 的酒石酸进行测试，用模拟液充满包装。保持包装密封，将溶液放入 100°C 水浴 2 小时或 120°C 高压釜中 30 分钟。</p> <p>Type B 类型 B</p> <p>Foods similar in composition to Type A, which do not</p>	<p>4.4. Determination of the specific migration of metals in packaging, lids, utensils and metallic equipment not covered by item</p> <p>测定第 4.1 条未涵盖的包装、盖子、器具和金属设备中金属的特定迁移。</p> <p>4.4.1. Simulants and sample preparation.</p> <p>模拟物和样品制备</p> <p>For acidic aqueous foods (<math>\text{pH} \leq 4.5</math>), the specific migration of metals into uncoated metallic materials should be performed using a 0.5% (m/v) citric acid solution as a simulant.</p> <p>对于酸性水性食品 (<math>\text{pH} \leq 4.5</math>)，金属向无涂层金属材料的特定迁移应采用 0.5% (m/v) 柠檬酸溶液作为模拟物进行。</p> <p>For non-acidic, alcoholic and fatty aqueous foods, the specific migration of metals into uncoated metallic materials should be performed using artificial water as a simulant. As an alternative, a 0.5% (m/v) citric acid solution may be used. If the result of the test performed using 0.5% citric acid solution (m/v) does not meet the limits, the test must be repeated using artificial water as a simulant.</p> <p>对于非酸性、含酒精和脂肪的水性食品，金属向无涂层金属材料的特定迁移测试应使用人造水作为模拟物进行。作为替代方案，可以使用 0.5% (m/v) 柠檬酸溶液。如果使用 0.5% 柠檬酸溶液 (m/v) 进行的测试结果不符合限值，则必须使用人造水作为模拟物重新进行测试。</p>



<p>undergo heat treatment. These foods must be tested with the same simulant as type A, keeping the packages for 24 hours at 80°C.</p> <p>成分与 类型 A 相似的食品，不经过热处理。这些食品必须使用与 A 类相同的模拟物进行测试，并将包装在 80°C 下保持 24 小时。</p> <p>Type C 类型 C</p> <p>Foods (beverages) with an alcohol content greater than 4%. These products must be tested with an aqueous solution of 8% ethanol, containing 0.5% of tartaric acid, keeping the package for 48 hours at 40°C.</p> <p>酒精含量大于 4% 的食品（饮料）。这些产品必须用含有 0.5% 酒石酸的 8% 乙醇水溶液进行测试，在 40°C 下保持 48 小时。</p> <p>4.4.2 In all cases, the gross free space of the packaging in the test must not exceed 6-7% of its total volume. The packaging must be hermetically closed, in the absence of air, for which conditioning with the heated solution, removal of air by mechanical means, inertization or other method that produces the same effect may be used.</p> <p>在所有情况下，测试中食品包装材料的总自由空间不得超过其总体积的 6-7%。食品包装材料必须密闭，处于无空气的情况下，为此可以使用加热溶液进行调节、通过机械方式去除空气、惰化或其他产生相同效果的方法。</p> <p>4.4.3 In the case of testing lids for glass packaging, the same procedure must be adopted, using the corresponding packaging in an inverted position so as to allow contact of the material under test with the simulant. In this case, when dealing with type A foods,</p>	<p>Preparation of artificial water (EN 16889:2016):</p> <p>人造水的制备 (EN 16889:2016) :</p> <p>Dissolve the following chemical substances in 1L of demineralized water:</p> <p>将以下化学物质溶解在 1L 软化水中:</p> <ol style="list-style-type: none"> <li>1. 14,3 mmol/l of <math>\text{NaHCO}_3</math> (1,2 g/l)</li> <li>2. 2,8 mmol/l <math>\text{MgSO}_4 \cdot 7 \text{H}_2\text{O}</math> (0,7 g/l)</li> <li>3. 8,0 mmol/l <math>\text{CaCl}_2 \cdot 2 \text{H}_2\text{O}</math> (1,2 g/l)</li> </ol> <p>Dilute 500 ml of this stock solution in a 10L container containing 7L of demineralized water. Stir for 10 minutes and adjust pH to 7.5 with 0.1M <math>\text{HNO}_3</math> or 0.1M <math>\text{NaOH}</math>. Fill it up to 10 L with demineralized water.</p> <p>在装有 7L 软化水的 10L 容器中稀释 500 毫升该储备溶液。搅拌 10 分钟并用 0.1M <math>\text{HNO}_3</math> 或 0.1M <math>\text{NaOH}</math> 将 pH 值调节至 7.5。用软化水填充至 10 L。</p> <p>The artificial water obtained has a total hardness of 0.53 mmol/l and a carbonated hardness of 0.36 mmol/l. The individual ionic concentrations are:</p> <p>所得人造水总硬度为 0.53 mmol/l，碳酸化硬度为 0.36 mmol/l。各个离子浓度为:</p> <p>Ca: 16,4 mg/l, Mg: 3,3 mg/l, <math>\text{HCO}_3^-</math>: 44 mg/l, Cl: 28,4 mg/l, <math>\text{SO}_4^{2-}</math>: 13 mg/l, Na: 16 mg/l.</p> <p>Permissible tolerances in artificial water are <math>\pm 20\%</math> for each ion.</p> <p>人造水中每种离子的允许偏差为 <math>\pm 20\%</math>。</p> <p>The artificial water obtained must be stored in sealed containers, closed so that the characteristics and components do not change. It is allowed to store for a maximum</p>
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	<p>the extraction conditions must be in a water bath for 2 hours at 100°C.</p> <p>对玻璃包装的盖子进行试验时，必须采用相同的程序，将相应的食品包装材料倒置，使待测材料与模拟物接触。在这种情况下，处理 A 类食品时，提取条件必须是在 100°C 的水浴中 2 小时。</p>	<p>of seven (7) days.</p> <p>所制得的人造水必须储存在密封容器中，密闭保存，使其特性和成分不会发生变化。最多可存放 7 天。</p> <p>Uncoated materials must be evaluated under actual conditions of use and, if not applicable, may be evaluated under the following conditions:</p> <p>未覆盖涂层材料必须在实际使用条件下进行评估，如果不适用，可以在以下条件下进行评估：</p> <ul style="list-style-type: none"> <li>- for use at room temperature for extended periods: ten (10) days at 40 °C.</li> <li>- 在室温下长时间使用：在 40 °C 下 10 天。</li> <li>- for use with hot fillings and short term storage (less than 24 hours) at room temperature: for 2 hours at 70 °C, followed by 24 hours at 40 °C.</li> <li>- 用于热灌装和在室温下短期储存（少于 24 小时）：70 °C 下 2 小时，然后 40 °C 下 24 小时。</li> <li>- for use with hot-fills and long-term storage (more than 24 hours) at room temperature: for 2 hours at 70 °C, followed by ten (10) days at 40 °C.</li> <li>- 用于热灌装和在室温下长期储存（超过 24 小时）：在 70 °C 下 2 小时，然后在 40 °C 下 10 天。</li> <li>- for use with boiling content, the article must be tested for 2 hours at the respective simulant's boiling temperature.</li> <li>- 用于盛装沸腾状的食品时，相关容器必须在相应模拟物的沸腾温度下测试 2 小时。</li> </ul> <p>The determination of the content of inorganic</p>
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		<p>elements in specific migration extracts must be carried out using spectrometric quantification techniques with adequate sensitivity to verify compliance with established limits.”</p> <p>必须使用具有足够灵敏度的光谱定量技术来测定特定迁移提取物中无机元素的含量，以验证是否符合既定限值。”</p>
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**Note 备注:**

*GMC Resolution no. 46/2006 Technical Regulation on provisions for metallic packaging, coatings, utensils, lids and equipment that are in contact with foodstuffs.*

GMC 第 46/2006 号决议 关于与食品接触的金属包装、涂层、器具、盖子和设备规定的技术法规。

PART 3 Toys and Children products **玩具和儿童产品**

8 USA - (Oregon) Prohibition of Crib Bumper Pads  
**美国 - （俄勒冈州）禁止婴儿床防撞床围**

The Governor of Oregon had signed HB 3379 which prohibit crib bumper pads or cribs equipped with crib bumper pads. The prohibition shall enter into force immediately.



俄勒冈州州长签署法案 HB 3379，禁止使用婴儿床防撞床围或配备婴儿床防撞床围的婴儿床。该禁令应立即生效。

The bill aimed to amend Oregon Revised Statutes (ORS) Section 646A.504 and 646A.506. Crib bumper pads are newly added in the prohibition of remanufacturing, retrofitting, selling, reselling, leasing, subletting, or placing in the stream of commerce in Oregon. In addition, crib equipped with crib bumper pads are considered as unsafe and shall be prohibited too.

该法案旨在修订俄勒冈州制定法修订本 (ORS) 第 646A.504 和 646A.506 节。在俄勒冈州禁止再制造、改造、销售、转售、租赁、转租或投放到商业活动的禁令中新增了婴儿床防撞床围。此外，配备婴儿床防撞床围的婴儿床被认为是不安全的，也应被禁止。

If a medical professional determines that there is a medically need to use crib bumper pads for a particular infant who uses a crib in a commercial place or public accommodation, the prohibition shall be waived in this case.

如果医疗专业人员确定因为医学上需要而应使用婴儿床防撞床围，则在商业场所或公共场供特定婴幼儿用的婴儿床所使用的婴儿床防撞床围可豁免于该禁令。



## PART 4 EU REACH 欧盟 REACH

### 9 EU - ECHA Proposes Restriction on Dechlorane Plus under REACH Annex XVII

#### 欧盟- 欧洲化学品管理局提议对得克隆(Dechlorane Plus)物质进行限制

On 23 June 2021, the European Chemical Agency (ECHA) has launched a public consultation on restricting the substance “Dechlorane Plus” in Annex XVII of the REACH Regulation. The proposed restriction would prevent the manufacturing, use and placing on the market of “Dechlorane Plus” and on articles containing Dechlorane Plus in concentrations equal to or greater than 0.1% by weight.

2021 年 6 月 23 日，欧洲化学品管理局 (ECHA) 提议将得克隆 (Dechlorane Plus) 物质加入 REACH 法规附录 XVII 加以限制，并开展公众咨询。提议禁止得克隆的生产、使用和投放市场，以及禁止含有得克隆浓度等于或超过 0.1%（以重量计）的物品的生产和投放市场。

Dechlorane Plus is a synthetic substance mainly used as a flame retardant in adhesives/sealants and polymers, and used as an extreme pressure additive in greases. It was identified by ECHA as a Substance of Very High Concern (SVHC) in 2018 because of its very persistent and very bioaccumulative (vPvB) properties. Dechlorane Plus shows structural similarities with already listed Persistent Organic Pollutants such as aldrin, chlordane, heptachlor, mirex, chlordecone, which have neurotoxic and some also carcinogenic properties.





得克隆(Dechlorane Plus)是一种人工合成物质，主要用作胶粘剂、密封剂和聚合物的阻燃剂，并用作油脂的添加剂。由于它具有非常持久性和非常生物累积性(vPvB)，它在 2018 年被欧洲化学品管理局(ECHA)确定为高度关注物质(SVHC)。得克隆与一些具有神经毒性和致癌性的持久性有机污染物(POPs)（如艾氏剂、氯丹、七氯、灭蚁灵、十氯酮）具有相似的结构。

#### The proposed restriction 提议的限制:

Designation of the substance of the group of substances or of the mixture 物质、物质组或混合物的名称	Conditions of restriction 限制情况
<p>1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10] octadeca-7,15-diene ("Dechlorane Plus") [covering any of its individual anti- and syn-isomers or any combination thereof]</p> <p>得克隆[包括所有反式和顺式异构体及其组合]</p> <p>CAS No 13560-89-9; 135821-74-8; 135821-03-3 EC No 236-948-9; -; -</p>	<p>1. Shall not be manufactured, or placed on the market as a substance on its own from [18 months after entry into force]. 从[法规生效后 18 个月]起，不得生产此物质，或将此物质投放市场。</p> <p>2. Shall not, from [18 months after entry into force], be used in the production of, or placed on the market in: 从[法规生效后 18 个月]起，不得将此物质用于生产，或投放市场：</p> <p>(a) another substance, as a constituent; 在另一种物质中，作为一种成分；</p> <p>(b) a mixture; 在混合物中；</p> <p>(c) an article, 在物品中</p> <p>in a concentration equal to or above 0.1% by weight. 浓度等于或超过 0.1%（以重量计）。</p>



The consultation on this proposed restriction starts on 23 June 2021 and ends on 3 January 2022. The final opinions of both Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) are scheduled to be available by June 2022. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

关于此项限制的公众咨询从 2021 年 6 月 23 日开始，将于 2022 年 1 月 3 日结束。风险评估委员会(RAC)和社会经济评估委员会(SEAC)的最终意见将计划在 2022 年 6 月底前公布。ECHA 将把两个委员会的联合意见提交至欧盟委员会，后者将最终决定是否将提议的限制项目加入 REACH 法规的附录 XVII 限制物质清单。

#### 10 EU -Eight New SVHCs Added to Candidate List for Authorisation, SVHC updated to 219

#### 欧盟- 8 项新物质被加入到高度关注物质清单，SVHC 总数增至 219 项

On 8 July 2021, the European Chemicals Agency (ECHA) has announced the SVHC Candidate List for authorisation as of July 2021, adding 8 new substances to the list. It now contains 219 substances.

2021 年 7 月 8 日，欧洲化学品管理局(ECHA)宣布将 8 种物质加入高度关注物质(SVHC)清单（候选物质清单）。高度关注物质清单现已包含 219 种物质。



Some of the newly added substances are used in consumer products such as cosmetics, scented articles, rubber and textiles. Others are used as solvents, flame retardants or to manufacture plastics products. Most have been added to the Candidate List because they are hazardous to human health as they are toxic for reproduction, carcinogenic, respiratory sensitisers or endocrine disruptors.

新加入的 8 种物质中，一些物质被用于消费品，例如化妆品、带香味的物品、橡胶和纺织品。另一些物质被用作溶剂、阻燃剂或用于生产塑料产品。这些物质被列入高度关注物质清单，是因为其具有生殖毒性、致癌性、呼吸系统致敏性或内分泌干扰性等特性，对人类健康有害。

Details of the addition to the list are as follows:

新加入候选清单的物质详细信息如下：

#	Substance name 物质名称	EC number EC 号	CAS number CAS 号	Reason for inclusion 列入原因	Examples of use(s) 示例用途
1	2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers 2-(4-叔丁基苄基)丙醛及其各立体异构体	-	-	Toxic for reproduction (Article 57 c) 生殖毒性（第 57c 款）	Cleaning agents, cosmetics, in scented articles, polishes and wax blends. 清洁剂，化妆品，在带香味的物品中，抛光剂和蜡混合物
2	Orthoboric acid, sodium salt 正硼酸钠	237-560-2	13840-56-7	Toxic for reproduction (Article 57 c) 生殖毒性（第 57c 款）	Not registered under REACH. May be used as solvent and corrosion inhibitor. 未在 REACH 法规下注册。



					可能被用作溶剂和腐蚀抑制剂。
3	<p>2,2-bis(bromomethyl)propane1,3-diol (BMP);</p> <p>2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA);</p> <p>2,3-dibromo-1-propanol (2,3-DBPA)</p> <p>2,2-双(溴甲基)-1,3-丙二醇 (BMP);</p> <p>三溴新戊醇(TBNPA);</p> <p>2,3-二溴-1-丙醇 (2,3-DBPA)</p>	<p>221-967-7,</p> <p>253-057-0,</p> <p>202-480-9</p>	<p>3296-90-0,</p> <p>36483-57-5,</p> <p>1522-92-5,</p> <p>96-13-9</p>	<p>Carcinogenic (Article 57a)</p> <p>致癌性 (第 57a 款)</p>	<p>BMP: manufacture of polymer resins and in one component foam (OCPF) application.</p> <p>TBNPA: polymer production manufacture of plastics products, including compounding and conversion and as an intermediate.</p> <p>DBPA: registered as an intermediate.</p> <p>BMP: 用于制造聚合物树脂和用在单组分泡沫 (OCPF)中;</p> <p>TBNPA: 生产聚合物, 生产塑料产品, 包括其混合和转化, 以及作为中间体;</p> <p>DBPA: 被注册为中间体</p>
4	<p>Glutaral</p> <p>戊二醛</p>	<p>203-856-5</p>	<p>111-30-8</p>	<p>Respiratory sensitising properties (Article 57f - human health)</p> <p>呼吸系统致敏性 (第 57f 款 - 对人类健康)</p>	<p>Biocides, leather tanning, x-ray film processing, cosmetics.</p> <p>生物杀灭剂, 鞣制皮革, 加工 X 射线胶片, 化妆品</p>
5	<p>Medium-chain chlorinated paraffins (MCCP) (UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17)</p>	-	-	<p>PBT (Article 57d)</p> <p>持久性、生物累积性及毒性(PBT) (第 57d 款)</p> <p>vPvB (Article 57e)</p>	<p>Flame retardants, plasticising additives in plastics, sealants, rubber and textiles.</p> <p>塑料、密封剂、橡胶和纺织品中的阻燃剂和塑化剂</p>



	中链氯化石蜡(MCCP) [由 80%或以上由碳链长度在 14 至 17 之间的线型含氯烷烃构成的 UVCB 物质]			非常持久性和非常生物累积性(vPvB) (第 57e 款)	
6	Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP) 酚的烷基化产物，带有经低聚合而富含 C12 支链或线型烷基链（主要是在对位），包括其每个异构体和/或它们的组合 (PDDP)	-	-	Toxic for reproduction (Article 57c) 生殖毒性（第 57c 款）  Endocrine disrupting properties (Article 57f - human health and environment) 内分泌干扰性（第 57f 款 - 对人类健康和对环境）  Carcinogenic (Article 57a) 致癌性（第 57a 款）  Equivalent level of concern having probable serious effects to the environment (Article 57f -environment) 可能对环境产生严重影响，造成同等程度关注（第 57f 款-对环境）	Preparation of lubricant additive materials and of fuel system cleaners. 制备润滑油添加剂材料和制备燃料系统清洁剂
7	1,4-dioxane 1,4-二氧六环	204-661-8	123-91-1	Equivalent level of concern having probable serious effects to human health (Article 57f - human health) 可能对人类健康产生严重影响，造成同等程度关注（第 57f 款-对人类	Solvent 溶剂



				健康)	
8	4,4'-(1-methylpropylidene)bisphenol 双酚 B	201-025-1	77-40-7	Endocrine disrupting properties (Article 57f - human health and environment) 内分泌干扰性 (第 57f 款 - 对人类健康和对环境)	Not registered under REACH. May be used in manufacture of phenolic and polycarbonate resin. 未在 REACH 法规下注册。 可能被用于制造酚醛树脂和聚碳酸酯树脂

From 5 January 2021, if SVHC substances are present in an article placed on the EU market in a concentration above 0.1 % w/w, the supplier of that article needs to submit a SCIP notification to ECHA under the Waste Framework Directive (WFD, Directive 2008/98/EC).

从 2021 年 1 月 5 日起，投放欧盟市场上的物品中的高度关注物质 (SVHC 物质) 浓度若超过 0.1% (质量分数)，则该物品的供应商须向欧洲化学品管理局(ECHA)进行 SCIP 通报。信息须提交至 SCIP 数据库。SCIP 通报是欧盟废弃物框架指令 (WFD, 指令 2008/98/EC) 对欧盟中的物品供应商的要求。

After 5 January 2021, if substances present in an article as such or in a complex object placed on the EU market in a concentration above 0.1 % w/w are added to the Candidate List, the supplier of that article need to submit a new SCIP notification or update a previous submitted SCIP notification for that article at the time of the next supply or placement on the market to any customer or as a result of an import, after the substance has been included in the Candidate List.



在 2021 年 1 月 5 日之后，若新物质被添加至高度关注物质候选清单(SVHCs)，且该物质在投放欧盟市场的物品或复杂对象中的浓度若超过 0.1%（质量分数），则该物品供应商需在下一次供应或投放市场给消费者时、或进口时，提交新的 SCIP 通报或更新先前提交的 SCIP 通报。

## PART 5 Others 其它

### 11 EU -Amends CLP Regulation to Lower Concentration Limits for Certain Boron Compounds

#### 欧盟- 修订 CLP 法规降低某些硼化合物的浓度限值

On 28 May 2021, the European Commission has published Commission Delegated Regulation (EU) 2021/849 to amend the CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. The amendment shall enter into force on 17 June 2021 and apply from 17 December 2022.

2021 年 5 月 28 日，欧盟委员会发布了授权法规(EU) 2021/849，修订法规(EC) No 1272/2008《物质和混合物的分类、标签和包装法规》（CLP 法规）。该修订在 2021 年 6 月 17 日生效，并将从 2022 年 12 月 17 日起执行。



The regulation has amended the Table 3 (List of harmonised classification and labelling of hazardous substances) of Part 3 of Annex VI to the CLP Regulation, to remove the specific concentration limits (SCL) of 7 Boron compounds. The generic concentration limit (GCL) for Repr. 1B substances, i.e. 0.3%, shall then apply for these Boron compounds. At or above which the presence of this substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.

该法规修订了 CLP 法规附件 VI 第 3 部分的表 3（《有害物质的统一分类和标签清单》），删除了 7 种硼化合物的特定浓度极限值(SCL)。这些硼化合物将适用于比以往更低的一般浓度极限值(GCL)：0.3%（类别 1B 生殖毒物(Repr. 1B)）。若这些硼化合物在另一种物质中，或在混合物中作为杂质、添加剂或单个成分的浓度大于或等于此浓度极限值(0.3%)，将使得另一种物质或混合物被分类为生殖毒物。

The Toy Safety Directive 2009/48/EC prohibits the use of CMR substances (substances that are classified as carcinogenic, mutagenic or toxic for reproduction) in toys. By way of derogation, substances or mixtures classified as CMR may be used in toys provided these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations in the CLP regulation, for the classification of mixtures containing these substances.





欧盟玩具安全指令 2009/48/EC 禁止在玩具中使用 CMR 物质（即被分类为致癌、致基因突变或具有生殖毒性的物质）。然而，作为豁免，若这些物质或混合物的单个浓度小于或等于 CLP 法规中所规定的，用于对含有这些物质的混合物进行分类的相关浓度，则允许在玩具中使用这些 CMR 物质或混合物。

Therefore, the concentration limit for those Boron compounds in toys or in components of toys shall become 0.3%, which is generic concentration limit triggering classification of a mixture for Repr. 1B substances. (Note: Toys or components of toys shall also comply with the migration limits for Boron (B) as laid down in Point 13 of Part III of Annex II to the Toy Safety Directive 2009/48/EC.)

因此，玩具和玩具部件中的这些硼化合物的浓度限值将降低为 0.3%（即类别 1B 生殖毒物引起混合物分类的一般浓度极限值）（注：玩具和玩具部件也须符合玩具安全指令 2009/48/EC 附件 II 第 III 部分第 13 点所规定的硼元素(B)迁移限值。）



The related Boron compounds are listed as below:

修订涉及的硼化合物如下：

Index No 索引号	Chemical Name 化学物质名称	CAS No CAS 号	Hazard Class and Category Code(s) 危害类别	Concentration limit in toy components 玩具部件中的浓度限值	
				Current 当前限值	New (Apply from 17 December 2022) 新限值 (从 2022 年 12 月 17 日起执行)
005-007-00-2	boric acid 硼酸	10043-35-3; 11113-50-1	Repr. 1B 类别 1B 生殖毒性	5.5 %	0.3%
005-008-00-8	diboron trioxide 三氧化二硼	1303-86-2	Repr. 1B 类别 1B 生殖毒性	3.1%	0.3%
005-011-00-4	tetraboron disodium heptaoxide hydrate 水合硼酸钠	12267-73-1	Repr. 1B 类别 1B 生殖毒性	4.5%	0.3%
	disodium tetraborate anhydrous 无水四硼酸钠	1330-43-4			
	orthoboric acid sodium salt 硼酸钠	13840-56-7			
	disodium tetraborate decahydrate 十水四硼酸钠 (硼砂)	1303-96-4		8.5%	



disodium tetraborate pentahydrate 氧化硼钠五水合物	12179-04-3		6.5%	
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Boron compounds have been used in the raw materials for producing slime and putty toys to make them more elastic and stretchable. Ingestion of boron compounds, in medium to high dosage, may induce nausea and vomiting and, in the long term, has an adverse effect on the fertility. Manufacturers shall control the boron compounds content in toy products to safeguard the safety of children.

硼化合物常被作为原料生产水晶泥(Slime)和泥团(Putty)玩具，使其更具有弹性和延展性。摄入中等剂量至高剂量的硼化合物，可能会引起人的恶心和呕吐。对硼化合物长期的摄入，将对生育能力造成不利影响。玩具制造商应控制玩具中的硼化合物含量，以保障儿童的安全。

Apart from Boron compounds, the Regulation (EU) 2021/849 also added, amended and deleted other substances in Table 3 of Part 3 of Annex VI of the CLP regulation. For detailed list of substances, please refer to link below:

除硼化合物外，法规(EU) 2021/849 还对 CLP 法规的附件 VI 第 3 部分的表 3 增加、修订、删除了其他物质。这些物质的详细列表请参阅以下链接: [Regulation \(EU\) 2021/849](#)



## 12 US Maine-Approved Prohibition of PFAS on Consumer Products

### 美国缅因州-批准禁止消费品中的 PFAS

The US Maine Legislature has passed Bill H.P.1113 - L.D. 1503 and adopt to a law which aimed to stop Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) pollution.

美国缅因州议会目前通过了法案 H.P.1113 - L.D. 1503 成为法律，旨在阻止全氟烷基和多氟烷基物质（PFAS）污染。

#### 1) Prohibition 禁止

The sale or distribution of the following products containing intentionally added PFAS shall be prohibited in Maines after the effective date:

在生效日期后，禁止在缅因州销售或分销以下含有故意添加的 PFAS 的产品：

	Effective date 生效日期
Carpet or rug 地毯或小地毯	1 January 2023 2023 年 1 月 1 日
Fabric treatment 织物处理物	1 January 2023 2023 年 1 月 1 日
Any consumer product 其它消费品	1 January 2030 2030 年 1 月 1 日



The prohibition on the consumer product can be exempted if it is determined that the use of PFAS is unavoidable currently.

如果确定目前无法避免使用 PFAS，则可免除对消费品的禁令。

## 2) Reporting 申报

Starting from 1 January 2023, for a product for sale in Maine containing intentionally added PFAS, the manufacturer shall submit a written notification to the Department of Environmental Protection:

从 2023 年 1 月 1 日起，对于在缅因州销售的含有故意添加的 PFAS 的产品，制造商应向环境保护部提交一份书面通报：

- A. A brief description of the product  
产品简要描述
- B. The purpose of PFAS used in the product  
PFAS 在产品中的用途
- C. The amount of each of the PFAS in the product  
产品中每种 PFAS 的含量
- D. The name, address, and the contact of the manufacturer  
制造商的名称、地址和联系方式
- E. Any additional information required by the department  
环境保护部要求的任何其他信息



### 3) Certificate of compliance 合格证书

When the Department of Environmental Protection suspects that the product contains intentionally added PFAS, the manufacturer is required to provide a certificate to prove that the product does not contain intentionally added PFAS.

当环境保护部怀疑产品含有故意添加的 PFAS 时，制造商需要提供证书以证明产品不含有故意添加的 PFAS。

#### Note 注

*Fabric treatment: a substance applied to fabric to give the fabric one or more characteristics, including but not limited to stain resistance or water resistance.*

**织物处理物：**应用于织物的一种物质，使织物具有一种或多种特性，包括但不限于防污性或防水性。



### 13 U.S. EPA-Proposes TSCA Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances

#### U.S. EPA-提议的 TSCA 对全氟烷基和多氟烷基物质的报告和记录保存要求

On June 28, 2021, the U.S. Environmental Protection Agency (EPA) published a notice of proposed rulemaking for reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS) under the Toxic Substances Control Act (TSCA) Section 8(a)(7). The proposed rule will require businesses that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.

2021 年 6 月 28 日，美国环境保护署（EPA）发布了关于《有毒物质控制法》TSCA）第 8(a)(7)节对全氟和多氟烷基物质（PFAS）进行报告和记录保存要求的拟议规则制定通知。拟议规则要求自 2011 年 1 月 1 日以来的任何一年里制造（包括进口）或已经制造这些化学物质的企业，以电子方式报告有关 PFAS 的用途、产量、处置、接触和危害的信息。

Proposed requirements will apply to all PFAS substances. The EPA has identified 1,346 PFAS on the TSCA Chemical Substance Inventory ("Inventory") as of April 2021, of which 669 substances are on the active Inventory. The proposed rule provides an illustrative list of substances subjected to the requirements.



拟议的要求将适用于所有 PFAS 物质。截至 2021 年 4 月，EPA 在 TSCA 化学物质名录（“名录”）中确定了 1346 种 PFAS，其中 669 种物质在活跃物质清单中。拟议的规则提供了一个说明性清单，列出了受要求约束的物质。

The reporting requirements apply not only to businesses that manufacture or import PFAS substances, but also when PFAS is present as byproducts, impurities or in articles (such as articles containing PFAS as part of surface coatings). And, notably, there is no de minimis or minimum volume of PFAS to trigger reporting, hence reporting would be required for PFAS even when only in trace amounts in an article.

报告要求不仅适用于制造或进口 PFAS 物质的企业，也适用于 PFAS 作为副产品、杂质或存在于物品中的情况（例如含有 PFAS 作为表面涂层一部分的物品）。而且，值得注意的是，没有规定触发报告的 PFAS 的最低限度或最小体积，因此，即使 PFAS 在物品中只有微量存在，也需要报告。

The submission period is proposed to be six months, which would begin six months following the effective date of the final rule, and the recordkeeping period is proposed to be 5 years, beginning on the last date of the submission period.

提交期建议为 6 个月，从最终规则生效之日起 6 个月开始；记录保存期建议为 5 年，从提交期的最后一天开始。





Public comment deadline for the proposed rule is August 27, 2021. In addition, the EPA has notified that comments pertaining to the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives them by July 28, 2021.

拟议规则的公众意见征询截止日期为 2021 年 8 月 27 日。此外，EPA 已通知，如果管理和预算办公室 (OMB) 在 2021 年 7 月 28 日之前收到与信息收集规定有关的意见，则最有可能予以考虑。

The proposed rule can be reviewed at:

可在以下网址查看拟议规则：

<https://www.govinfo.gov/content/pkg/FR-2021-06-28/pdf/2021-13180.pdf>

#### 14 US FTC- Publishes Final Rule of 'Made in USA' Labelling Rule (16 CFR 323)

**美国联邦贸易委员会 FTC- 发布“美国制造”标签的最终法规  
(16 CFR 323)**

On July 16, 2021. The Federal Trade Commission (FTC) has issued a final rule related to “Made in USA” and other unqualified U.S. origin claims on product labels. This final rule is effective 13 August 2021.



2021 年 7 月 16 日，美国联邦贸易委员会（FTC）发布了一项关于产品标签上的“美国制造”和其它不合格美国原产地声称的最终法规。这一最终法规将于 2021 年 8 月 13 日生效。

The rule covers labels on products that make unqualified MUSA claims. It codifies the Commission's previous MUSA Decisions and Orders and prohibits marketers from making unqualified MUSA claims on labels unless:

这项法规涵盖了不合格 MUSA 声称的产品标签。它将委员会以前的 MUSA 决定和法令编成法典，并禁止销售人员在标签上印制不合格的 MUSA 声称，除非：

- Final assembly or processing of the product occurs in the United States 产品的最终组装或加工在美国进行
- All significant processing that goes into the product occurs in the United States, and 所有产品的主要加工过程在美国进行，以及
- All or virtually all ingredients or components of the product are made and sourced in the United States.

产品的所有或几乎所有成分或部件均在美国制造和采购。

The rule also covers labels making unqualified MUSA claims appearing in mail order catalogs or mail order advertising. To avoid confusion or perceived conflict with other country-of-origin labeling laws and



regulations, it does not supersede, alter, or affect any other federal or state statute or regulation relating to country of origin labels, except to

the extent that a state country of origin statute, regulation, order, or interpretation is inconsistent with the rule.

这项法规还包括出现在邮购目录或邮购广告中的不合格 MUS 声称的标签。为避免与其它原产国标签法律和法规产生混淆或冲突，它不取代、改变或影响任何其它与原产国标签有关的联邦或州法规或条例，除非原产国法规、条例、法令或解释与本法规不一致。

MUSA: made in USA 美国制造

## 15 Egypt – Approved to Mandate Standards for Certain Products

### 埃及 - 批准对某些产品的强制执行标准

The Ministry of Trade and Industry has issued Ministerial Decrees No.221/2021 and No.223/2021 to mandate Egyptian standards for certain products including toys, playpen, paints, glass containers, cookware, cosmetics and outdoor furniture.



埃及贸易和工业部发布第 221 / 2021 号和第 223 / 2021 号部长令，要求对某些产品（包括玩具、婴儿围栏、油漆、玻璃容器、炊具、化妆品和户外家具）强制执行的埃及标准。

By 14 December 2021, those products importing into Egypt shall comply with the following standards:

不迟于 2021 年 12 月 14 日，埃及的进口产品应符合以下标准：

- 1) ES 8284-2 Outdoor furniture - seating and tables for camping, domestic and contract use Part 2: Mechanical safety requirements and test methods for seating  
户外家具 - 露营、家用和合同使用的座椅和桌子 第 2 部分：座椅的机械安全要求和测试方法
- 2) ES 8462 Furniture - Operating mechanisms for seating and sofa-beds - Test methods  
家具 - 座椅和沙发床的操作机制 - 测试方法
- 3) ES 5884-1 Cosmetics - oils Part 1: individual oils for direct use  
化妆品 - 油 第 1 部分：直接使用的油
- 4) ES 3570 Cosmetics - perfumed liquid  
化妆品 - 芳香液
- 5) ES 3123-1 Safety of toys - Part 1: Mechanical and physical properties  
玩具安全 - 第 1 部分：机械和物理特性
- 6) ES 446 Glass containers and accessories used for pharmaceutical tablets  
用于片状药剂的玻璃容器和附件



- 7) ES 2925-1 Ophthalmic optics – uncut finished spectacle lenses Part 1: Specifications for single vision and multifocal lenses

眼科光学元件 - 未切割成品眼镜片第 1 部分：单光和多焦点镜片规范

- 8) ES 2925-2 Ophthalmic optics – uncut finished spectacle lenses Part 2: Specifications for progressive power lenses

眼科光学元件 - 未切割成品眼镜片第 2 部分：渐进屈光力镜片规范

- 9) ES 1539 Paints and varnishes - Requirement of emulsion water based paints for interior and exterior surfaces

油漆和清漆 - 内表面和外表面用乳胶水性涂料的要求

- 10) ES 573 Aluminum cookware used above stoves, ovens, or food warming areas

用于炉灶、烤箱或食物加热的铝制炊具

- 11) ES 8467 Playpens for domestic use - Safety requirements and test methods

家用游戏围栏 - 安全要求和测试方法

According to the Egyptian standardization body, the current standards and their references are:

根据埃及标准化机构的说明，当前的标准及其参考如下：

- 1) ES 8284-2:2021 (EN 581-2/2015 AC :2016)
- 2) ES 8462:2021 (EN 13759 /2012)
- 3) ES 5884-1:2021 (British pharmacopoeia 2007)



- 4) ES 3570:2021 (EC No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products)
- 5) ES 3123-1:2021 (EN 71-1/2014+A1/2018)
- 6) ES 446:2021 (ISO 11418-4/2005 (Confirm2019) Containers and Accessories for Pharmaceutical Preparations – Part 4 : Tablet Glass Bottles)
- 7) ES 2925-1:2015 (ISO 8980-1/2004,cor1:2006 Ophthalmic optics – uncut finished spectacle lenses Part 1: Specifications for single-vision and multifocal lenses)
- 8) ES 2925-2:2015 (ISO 8980-2/2004,cor1:2006)
- 9) ES 8467:2021 (BS EN 12227/2010)

## 16 Hong Kong - Approved Mercury Control Ordinance

### 中国香港 - 批准汞管制条例

The Hong Kong Government has issued Mercury Control Ordinance. The Ordinance aimed to implement the Minamata Convention on Mercury. It shall already enter into force.

香港政府已颁布汞管制条例。该条例旨在实施《关于汞的水俣公约》。该条例已经生效。



### 1) Prohibition 禁止

Importing, exporting, manufacturing of mercury-added on products, including battery and cosmetic\*, shall be prohibited, with some exemptions. Detail list of mercury-added on products is mentioned in Schedule 3. Supplying of mercury-added on products shall be prohibited after 2 July 2024.

除一些豁免，禁止进口、出口、制造添加汞的产品，包括电池和化妆品\*。添加汞的产品的详细清单见附表 3。2024 年 7 月 2 日后禁止提供添加汞的产品。

The prohibition of mercury-added on products shall not apply to

添加汞的产品的禁令不适用于：

- Pesticide 杀虫剂
- Waste 废弃物
- Chinese herbal 中草药
- Article in transit 过境物品
- Thing that is an air transshipment cargo 空运货物
- Thing that is brought in Hong Kong by a person  
由个人带入香港的物品

The prohibitions of mercury substance are also mentioned in the Ordinance.

该条例亦提及禁止使用含汞物质。



Other requirements of export permit, import permit and possession permit are mentioned in the Ordinance as well.

该条例还提及出口许可证、进口许可证和管有许可证的其他要求。

#### Note 注

*Cosmetics having a mercury content exceeding 1 ppm*

汞含量超过 1 ppm 的化妆品

1) *including skin lightening soap and cream*

包括美白皂和美白霜; and 以及

2) *excluding a cosmetic product that is intended by its manufacturer to be applied only in the vicinity of the eyes*

不包括生产制造后仅意图用于眼部区域的化妆品, and 以及

A. *that contains mercury as preservative*

采用汞作为防腐剂的含有汞产品;

B. *for which no effective and safe substitute for preservative is available*

目前没有有效和安全的防腐剂替代品; and 且

C. *that has a mercury content  $\leq 70$  ppm*

汞含量 $\leq 70$  ppm.





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