

## FOOD CONTACT DECLARATION

***It is the responsibility of our customers to check if the materials supplied by SABIC and articles made out of it are suitable for the intended use and comply with all applicable regulations and requirements.***

As a producer of **plastic intermediate materials**, SABIC confirms that **SABIC® LLDPE R50035 - 00900** has been formulated and manufactured in accordance with the relevant requirements of the following food contact recommendations or regulations:

### Europe

#### **Netherlands**

Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen).

Chapter I – Kunststoffen.

#### **Germany**

Empfehlung III "Polyethylen" of Kunststoffe im Lebensmittelverkehr: Empfehlungen des Bundesinstituts für Risikobewertung (BfR) (former BgVV).

Status: June 2019.

Bedarfsgegenständeverordnung in der Fassung der Bekanntmachung vom 23 December 1997, latest amendment February 15, 2016 (BGBl. I S. 198).

#### **European Union (EU)**

Regulation (EC) No 1935/2004 of the European Parliament and of the Council for the following aspects:

- **Traceability**

Systems are in place that identify suppliers and customers one step forward / one step back in the value chain.

- **Declaration of Compliance / Supporting Documentation**

This material will be accompanied by a written declaration, stating it complies with the relevant applicable food contact rules. Appropriate supporting documentation is available for competent authorities on their demand to demonstrate such compliance. This documentation will be renewed in case of substantial changes.

- **Good Manufacturing Practice (GMP)**

This material has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

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- **Specific Measures**

All components that comprise **SABIC® LLDPE R50035 - 00900** are either listed or exempted from listing according to Commission Regulation (EU) No 10/2011, regulating plastic materials and articles intended to come into contact with food, up to and including **Commission Regulation (EU) No 2020/1245**.

In accordance with the requirement described in Annex IV of Commission Regulation (EU) No 10/2011 to disclose adequate information about substances that are subject to restrictions and/or specifications set out in Annexes I and II to the aforementioned Regulation, we refer to the information given at the end of this document.

**Overall Migration Limit (OML) testing**

To determine the OML, migration experiments have been carried out using test plaques as test specimen (1.6 mm, S/V ratio 6 dm<sup>2</sup>/kg) made of **SABIC® LLDPE R50035 - 00900** or a comparable grade, in food simulants B, C and D2 (according to Table 1 of Annex III of Commission Regulation (EU) No 10/2011) under testing conditions covering long term storage above 6 months at room temperature and below, including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes (OM2 in Table 3, Annex V of Commission Regulation (EU) No 10/2011).

**Specific Migration Limit (SML) testing**

For substances regulated with a SML and listed in Attachment "Substances subject to restrictions or specifications", SML migration estimates following a worst-case calculation, assuming 100% migration, or migration modelling using an EU-recognized mathematic migration model, or migration experiments during 10 days at 60°C, using test plaques as test specimen (1.6 mm, SV ratio 6 dm<sup>2</sup>/kg) made of **SABIC® LLDPE R50035 - 00900** or a comparable grade, in food simulants B, C and D2 (according to Table 1 of Annex III of Commission Regulation (EU) No 10/2011) have been carried out.

**Test summary**

Results have shown that under mentioned conditions migration limits (overall and if applicable specific) were not exceeded.

**Compliance work to be performed by the downstream operator**

In accordance with the guiding principles to avoid duplication of compliance work and to conduct compliance work as early as possible in the manufacturing chain, SABIC has conducted hazard assessments in accordance with Article 19 of Commission Regulation (EU) No 10/2011, under standard conditions on standard test specimens. Due to its position as a raw material supplier, SABIC cannot assess exposure under every actual or foreseeable condition of use of the finished article, wholly or partly composed of **SABIC® LLDPE R50035 - 00900**.

However, in order to support our customers to conclude on their own compliance work required by Article 3(1)(a) of Regulation (EC) No 1935/2004, upon specific request, based on customer's exposure assessment, SABIC may provide hazard information relevant for **SABIC® LLDPE R50035 - 00900**.

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**Non EU countries****Switzerland**

Swiss ordinance on materials and objects in contact with food: SR 817.023.21 „Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen (Bedarfsgegenständeverordnung) vom 16. Dezember 2016, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff“; amended by „Verordnung des EDI vom 19. November 2020 (I, II)“ (AS 2020 4811).

Status: December 1, 2020.

**Americas****United States of America (USA)**

The resin comprising **SABIC® LLDPE R50035 - 00900** is listed in the Code of Federal Regulations (CFR), Title 21, paragraph 177.1520 (olefin polymers), issued by the Food and Drug Administration (FDA).

All adjuvants are cleared according to CFR Title 21, part 178 (Indirect food additives), are generally recognised as safe (GRAS), are prior-sanctioned food ingredients, are cleared on basis of regulations for food additives of before 1958 or are cleared via a Food Contact Notification (FCN).

This material may be used **under conditions of use B – H** as described in Table 2 of the Code of Federal Regulations (CFR), issued by the Food and Drug Administration (FDA), Title 21, paragraph 176.170(c) in contact with **all types of food** as described in Table 1 of CFR, Title 21, paragraph 176.170(c). The material must of course be technically suitable for the intended use.

When contacting **types of food III, IV-A, V, VII-A and IX**, as described in Table 1 of CFR, Title 21, paragraph 176.170(c), the finished articles are to have a volume of at least 18.9 liters (5 gallons).

Status: February 1, 2022.

**MERCOSUR (Argentina, Brazil, Paraguay, Uruguay, Venezuela)**

Monomers in **SABIC® LLDPE R50035 - 00900** are listed on Resolution GMC No. 02/12 “Reglamento Técnico Mercosur sobre lista positiva de monómeros, otras sustancias de partida y polímeros autorizados para la elaboración de envases y equipamientos plásticos en contacto con alimentos” and amendments up to and including Resolution GMC No. 19/21.

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Additives in **SABIC® LLDPE R50035 - 00900** are listed on Resolution GMC No. 39/19 “Reglamento Técnico Mercosur sobre lista positiva de aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos en contacto con alimentos”.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned regulations, please refer to the information given at the end of this document.

### ***Brazil***

Monomers in **SABIC® LLDPE R50035 - 00900** are listed on Resolution - RDC No. 56/2012 “Resolução da Diretoria Colegiada sobre a lista positiva de monômeros, outras substâncias iniciadoras e polímeros autorizados para a elaboração de embalagens e equipamentos plásticos em contato com alimentos” and amendments up to and including Resolution - RDC No. 589/21.

Additives in **SABIC® LLDPE R50035 - 00900** are listed on Resolution - RDC No. 326/2019 “Resolução da Diretoria Colegiada sobre a lista positiva de aditivos destinados à elaboração de materiais plásticos e revestimentos poliméricos em contato com alimentos e dá outras providências”.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned regulations, please refer to the information given at the end of this document.

### ***Canada***

A Letter of No Objection (LoNO) of the Chemical Health Hazard Assessment Division of the Bureau of Chemical Safety of Health Canada has been received for the use of **SABIC® LLDPE R50035 - 00900** in food contact applications.

### **Asia Pacific**

#### ***The People’s Republic of China (PRC)***

#### **GB4806.1-2016**

PRC National Standard GB4806.1-2016 “General safety requirements for food contact materials and articles”, as applicable to plastic basic resins, for the following aspects:

- **Traceability**

Systems are in place that identify suppliers and customers one step forward / one step back in the value chain.

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- **Product information**

When supplied to China, the material packaging will contain (in Chinese language): product name and material type; name, address and contact details of manufacturer and/or seller; date of manufacture and reference to declaration of compliance with relevant applicable Chinese standards.

- **Declaration of Compliance / Supporting Documentation**

This material will be accompanied by a written declaration, stating it complies with the relevant applicable Chinese food contact standards.

Appropriate supporting documentation is available for competent authorities on their demand to demonstrate such compliance. This documentation will be renewed in case of substantial changes.

- **Specific measures**

All components that comprise **SABIC® LLDPE R50035 - 00900** are either listed or exempted from listing according to PRC National Standards GB4806.6-2016 and GB9685-2016, regulating plastic materials and articles intended to come into contact with foodstuffs.

**Note:** Annex A.1 of PRC National Standard GB4806.6-2016 specifies a list of approved polymer resins with their chemical name and CAS RN. It also specifies the generic class and name of restricted monomers (if any) and corresponding SML/QM levels. PRC National Standard GB4806.6-2016 does not list CAS RN or GB9685-2016 FCA number of restricted monomers. Considering the complexity of monomer chemical names, if a restricted monomer's GB9685-2016 FCA number is available, SABIC will provide this identification number and its corresponding SML/QM level. QM levels will be consistent between GB4806.6-2016 and GB9685-2016 (if available).

- **Basic requirements**

In accordance with the guiding principles to avoid duplication of compliance work and to conduct compliance work as early as possible in the manufacturing chain, SABIC has conducted hazard assessments in accordance with section 3.1 under standard conditions on standard test specimens. Due to its position as a raw material supplier, SABIC cannot assess exposure under each and every actual or foreseeable condition of use of the finished article, wholly or partly composed of **SABIC® LLDPE R50035 - 00900**.

However, in order to support our customers to conclude on their own compliance work required by section 3.1, upon specific request, based on customer's exposure assessment, SABIC may provide hazard information relevant for **SABIC® LLDPE R50035 - 00900**

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- **Good Manufacturing Practice (GMP)**

This material has been manufactured outside the People's Republic of China, but in accordance with the relevant requirements of the European Commission Regulation (EC) No. 2023/2006 on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food. These requirements are similar to the requirements of PRC National Standard GB 31603-2015 (Chinese GMP standard).

**GB4806.6-2016**

**SABIC® LLDPE R50035 - 00900** contains the following resin(s) that is (are) listed in PRC National Standard GB 4806.6-2016, Table A.1, and complies with any applicable requirements for that (those) resin(s):

- Entry 101 (polyethylene copolymer, CASRN 25087-34-7).

**GB9685-2016**

All intentionally added additives used in the production of **SABIC® LLDPE R50035 - 00900** that are subject to PRC National Standard GB 9685-2016 regulating the use of additives in food contact materials and products:

- are listed in Table A.1 of PRC National Standard GB 9685-2016, or are listed in Table A.2 of PRC National Standard GB 2760-2014, regulating the use of food additives,
- or are approved via NHC Approval Notices with corresponding application scope and specific requirements.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned standards, please refer to the information given at the end of this document.

**Malaysia**

Monomers and additives in **SABIC® LLDPE R50035 - 00900** are listed as authorised on Annex A and B, respectively, of Malaysian standard MS 2234:2009 on Plastics materials and articles intended to come into contact with food.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned standard, please refer to the information given at the end of this document.

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### ***The republic of India***

**SABIC® LLDPE R50035 - 00900** comprises a basic resin that is listed in Indian Standard IS 16738:2018 (Positive List of Constituents of Polyethylene and Polypropylene in Contact with Foodstuffs, Pharmaceuticals and Drinking water), superseding IS 10141:2001 and IS 10909:2001.

The intentionally added additives used in **SABIC® LLDPE R50035 - 00900** are listed in Indian Standard IS 16738:2018 (Positive List of Constituents of Polyethylene and Polypropylene in Contact with Foodstuffs, Pharmaceuticals and Drinking water), superseding IS 10141:2001 and IS 10909:2001.

**SABIC® LLDPE R50035 - 00900** does not contain additives with a migration limit as mentioned in Table 1 of the Indian Food Safety and Standards (Packaging) Regulations 2018 of December 24, 2018.

For adequate information about substances that are subject to restrictions and/or specifications set out in the aforementioned standard, please refer to the information given at the end of this document.

### ***Japan***

The base resin and monomers of, and the additives contained in **SABIC® LLDPE R50035 - 00900** are listed in the latest official version of Appendix 1, Table 1 (1) (base resin list) and Table 2 (additives list) as part of the "Partial revision of the standards for foods, additives, etc. (Ministry of Health, Labor and Welfare Notification No. 196", promulgated on April 28, 2020, by the Japanese Ministry of Health, Labour and Welfare (MHLW), available on [https://www.mhlw.go.jp/stf/newpage\\_05148.html](https://www.mhlw.go.jp/stf/newpage_05148.html)

The latest published lists are available for download through the following links:

MS Excel format : [20210818\\_Draft list of base polymers](#)  
[20210818\\_Draft list of monomers](#)  
[20210818\\_Draft list of additives](#)

The substances listed in Appendix 1 (the Positive List (PL)) are those selected by the MHLW based on information at present time. New substances may be added and the current information or regulations in the list may be revised.

The links provided refer to draft versions and are merely for information purposes.

At this point in time, only the officially published lists of April 28, 2020 are legally binding.



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## **General information**

We request you to use information contained in this document for compliance purposes only.

We wish to stress that test results referred to in this declaration are performed under standard conditions on standard test specimens. These may differ significantly from the performance of the finished plastic material or article under the actual and foreseeable conditions of use and may not be used to demonstrate regulatory compliance of finished articles.

SABIC has no control over finished articles nor over their manufacturing, processing and use conditions and can never accept any responsibility for the compliance of these finished articles. SABIC cannot be held responsible for changes that may result from further processing of its product by others. It is the responsibility of the downstream users to check the compliance of their product with the relevant regulations and to validate material performance in the end application through proper end use testing based on the information provided by the supply chain.

This declaration is restricted to **SABIC® LLDPE R50035 - 00900** as it leaves the production facilities. This declaration does not cover:

- Any substance subsequently added by downstream users.
- Poor material or finished article due to inexperienced manufacture by downstream users.
- Any negative influence of the finished article on the organoleptic properties of the packaged food

Please note carefully that Regulations develop continuously and that SABIC declarations may be adapted accordingly. This declaration replaces all previous versions relating to this subject and product, and will be valid for a period of 1 (one) year, after which it will automatically expire.

If you have any further questions, or require any additional information on the above, please use the "[Contact Us](#)" form on the SABIC website. Select "[Regulatory](#)" as option under "[What is the nature of your inquiry](#)". The form is available via <https://www.sabic.com/en/contact>.

## **Corporate Product Stewardship** Saudi Basic Industries Corporation

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## **Attachment**

We request you to use the identity and information of disclosed substance(s) for compliance purposes only.

### **SUBSTANCES SUBJECT TO RESTRICTIONS OR SPECIFICATIONS**

References to substance identifications in this section come from Annex I of EU Regulation (EU) 10/2011 (FCM substance No), PRC National Standard GB9685-2016 (FCA number) and/or US FDA Code of Federal Regulations (CFR), Title 21.

This material contains the following monomers or additives that are regulated with a restriction or specification in their use:

- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CASRN 2082-79-3), which is regulated with a specific migration limit of 6 mg/kg food in the EU (FCM substance No 433) and China (FCA0576). In the USA, this substance is listed in CFR, Title 21, paragraph 178.2010.
- Zinc compound(s), which is/are regulated with a specific migration limit of 25 mg/kg food (expressed as Zinc) in China and India, except in the EU where this limit is 5 mg/kg food.

This material contains the following additives that are regulated as dual use additives in Europe:

- None.

Based upon information received from raw material suppliers or manufacturers and/or knowledge of the presence of genotoxic substances, we can inform you that SABIC® LLDPE R50035 - 00900 does not contain intentionally added genotoxic substances, originating from the used raw materials in the manufacturing process or degradation products thereof, that foreseeably give rise to a migration from the final material > 0.00015 mg/kg food simulant, determined by a worst-case calculation (assuming 100% migration), or migration modelling using an EU-recognized mathematic migration model, or migration experiments during 10 days at 60°C using standard test specimens, an SV ratio of 6 dm<sup>2</sup>/kg and standard food simulants (according to Table 1 of Annex III of Commission Regulation (EU) No 10/2011).

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**备注:** 此中文版文件系为方便客户而提供，请结合英文版阅读。如因中英文版本存在差异，请以英文文本为准。

按中国GB4806.1-2016《食品安全国家标准 食品接触材料及制品通用安全要求》的相关规定，对前文涉及的中国食品接触材料符合性声明部分，翻译如下：

### 食品接触材料声明

客户有责任确认，SABIC 提供的材料和以 SABIC 提供的材料为原料而制造的产品是否适合预期的用途，并符合相关的法规、规章与标准要求。

SABIC,作为塑料中间材料的制造商，确认 SABIC® LLDPE R50035 - 00900 产品是按如下食品接触材料推荐或法规的有关要求，规范产品配方并生产：

### 亚太地区

#### 中华人民共和国

#### GB4806.1-2016

中国国家标准GB4806.1-2016《食品安全国家标准 食品接触材料及制品的通用安全要求》在以下方面适用于塑料基础树脂：

- **可追溯性**

我司已建立了产品可追溯体系，以追溯价值链中前/后步骤的供应商和客户。

- **符合性声明/支持性文件**

我司将提供该材料的书面符合性声明，声明该材料符合有关食品接触材料法规要求。

在主管机构的特别要求时，我司将提供符合性声明相关的支持性文件，以证明其合规性。如发生重要变化时，我司将及时更新支持性文件。

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- **产品信息**

供应至中国的材料的包装袋上将包含如下（用中文书写的）信息：产品名称和材料类型，生产者和/或经销商的名称、地址和联系方式，生产日期，以及符合相关适用的中国标准的声明。

- **特殊规定**

SABIC® LLDPE R50035 - 00900 产品的所有组分，均符合GB4806.6-2016《食品安全国家标准 食品接触用塑料树脂》、GB9685-2015《食品安全国家标准 食品接触材料及制品用添加剂使用标准》和相关NHC(中国卫健委)公告的限制规定，或可按相关食品安全国家标准规范而豁免。

**备注：**GB 4806.6-2016《食品安全国家标准 食品接触用塑料树脂》批准了中国允许使用的树脂清单，该标准的附表A.1 规定了每个聚合物的化学名、化学文摘号 (CAS RN)、通用类别名、限制性单体的化学名称及其SML/QM限量。该标准中未给出限制性单体的化学文摘号 (CAS RN) 或中国国标GB9685-2016 FCA物质编号。考虑到单体化学名称的复杂性，如果一个单体在GB9685-2016中存在FCA 物质编号，SABIC 除了明示限制性单体名称外，也会公布GB9685-2016 FCA物质编号，该单体的SML/QM限量水平会与GB4806.6-2016 和 GB9685-2016(如存在) 一致。

- **基本要求**

根据食品接触用材料安全指导原则，为避免重复的合规工作以及尽早在制造链中开展合规工作，按照该标准第3.1节的要求，SABIC已使用标准测试样品在标准条件下进行了危害安全评估。但作为原材料供应商，SABIC无法评估由全部或部分的SABIC® LLDPE R50035 - 00900产品组成的制成品在实际或者预期可能的所有使用条件的暴露情况。

尽管如此，为了支持我们的客户能够按照该标准第3.1节的要求完成具体客户的合规工作，当特别提出要求时，基于客户提供的暴露场景资料，SABIC可能会提供SABIC® LLDPE R50035 - 00900产品相关的危害信息。

- **良好生产规范 ( GMP )**

该产品在中国境外生产，其生产过程符合欧盟委员会(EC) 第 2023/2006号法规-关于预期接触食品的材料和制品的良好生产规范(GMP)的相关要求。这些要求与GB 31603-2015《食品安全国家标准 食品接触材料及制品生产通用卫生规范》(中国GMP标准)的相关要求相似。

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**GB4806.6-2016**

**SABIC® LLDPE R50035 - 00900** 产品中的树脂列于GB4806.6-2016《食品安全国家标准 食品接触用塑料树脂》附录A.1, 并且符合所有对该树脂的相关要求。:

- 第101号树脂, 通用类别名 PE, 化学文摘号 25087-34-7。

**GB9685-2016**

**SABIC® LLDPE R50035 - 00900** 产品中的所有有意添加使用的添加剂均符合GB9685-2016《食品安全国家标准 食品接触材料及制品用添加剂使用标准》的相关规定:

- 列于GB9685-2016《食品安全国家标准 食品接触材料及制品用添加剂使用标准》之表A.1(食品接触用塑料材料及制品中允许使用的添加剂及使用要求)·或列于GB2760-2014《食品安全国家标准 食品添加剂使用标准》之表A.2(可在各类食品中按生产需要适量使用的食品添加剂名单)·
- 或经中国国家卫生健康委员会(NHC)相关批准公告(包括相应的应用范围和特别要求)批准。

有关上述标准涉及的添加剂的限值和/或规格要求的详细信息, 请见本文末尾。

**一般信息**

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## 附件

我司要求贵司对本章节信息严格保密，对所披露物质的标识信息仅用于合规之目的。

### 有特殊迁移的限制物质或有规格限制的物质(SML/QM)

本节中提及的物质标识源自欧盟法规(EU) 10/2011 FCM物质编号、中国 GB9685-2016 FCA物质编号、印度食品安全和标准 (包装) 法规2018和/或美国食品和药物管理局联邦法典(CFR)第21章节之规定。

本产品使用时，涉及如下有 SML/SML(T) 限制, QM 限制和/或其它限制的单体或添加剂。

- $\beta$ -(3,5-二叔丁基-4-羟基苯基)丙酸十八醇酯 (CAS RN 2082-79-3), 欧盟FCM No. 433, 中国FCA0576, 特殊迁移限量 SML = 6 mg/kg (食品)。该物质经美国联邦法典21CFR第178.2010章节批准。
- 含锌化合物 欧盟PIM法规规定的特殊迁移限量 SML = 5 mg/kg (食品)(以锌计)，中国GB9685标准规定的特殊迁移限和印度食品安全和标准 (包装) 法规2018量 SML = 25 mg/kg (食品) (以锌计)。

本产品含以下欧盟法规规定的双用途类添加剂(即可能被同时用于食品直接添加剂及食品接触材料的添加剂)：

- 无

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