



Henkel AG & Co. KGaA, 40191 Düsseldorf, Deutschland

To all customers

Datum / Date 31.01.2025

Ihre Nachricht /

Your message

Abteilung / Dept.

Telefon / Phone

Telefax / Fax

E-Mail / E-mail

Valentina.Zanni@henkel.com

Dear Sir or Madam,

Referring to your request concerning the food contact status we can declare the following for our European<sup>1</sup> adhesive TECHNOMELT SUPRA 100 (SDS no.: 105502):

### **Framework Regulation**

According to the definition in article 1 of the Framework Regulation (EC) No 1935/2004 this regulation is valid for materials in the finished state.

Article 3 of the Framework Regulation (EC) No 1935/2004 requires that materials and articles, coming into contact with food, shall be manufactured in such a way that they do not endanger human health, do not cause an unacceptable change in the composition of the food and do not change the organoleptic characteristics of the food. This means that the final product must be assessed when checking compliance with the respective regulation. The testing of only one element, e.g. the adhesive, which moreover represents only a small part of the total packaging, is not the right approach to evaluate compliance with the respective food regulations. Due to the wide range and diversity of packaging materials (different foils, inks etc.) we cannot test the special conditions of each customer. The organoleptic characteristics can be monitored only on the packaged foodstuff and therefore fall under the responsibility of the adhesive user.

In reference to article 17 of the Regulation (EC) No 1935/2004 we can declare a full traceability of materials and articles intended to come into contact with food from supplier and raw material batch to

<sup>1</sup> EU, Switzerland, Norway, UK

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the delivered product, because our production sites are accredited to ISO 9001 and thus we document all our production activities providing availability to appropriate authorities.

As currently no specific measure for adhesives exists, article 16 of the Framework Regulation allows the use of national provisions for the assessment of food contact. One of the already existing specific measures is the regulation on plastic materials and articles intended to come into contact with foodstuffs (EU) No 10/2011, replacing the Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs and its amendments on 1<sup>st</sup> May 2011.

### **GMP Regulation**

Food contact legislation requires, that materials and articles intended to come into contact with food shall be manufactured in compliance with good manufacturing practice. As our manufacturing sites are accredited to ISO 9001, we have established an effective quality assurance and quality control system. By means of a hazard analysis and critical control point analysis, a hazard identification and a risk assessment were conducted for the manufacturing sites in which we produce the above mentioned product for food packaging. This ensures, that we are able to control and monitor our finished good from raw materials to product distribution.

Our process documentation of each manufacturing stage enables us to provide the appropriate authorities with the necessary information at any time.

Therefore, we can confirm that our above mentioned product is manufactured in accordance with the principles of good manufacturing practice.

Specifically, we can confirm that our above mentioned product is manufactured in compliance with the Regulation (EC) No 2023/2006 on good manufacturing practice (GMP Regulation).

### **Plastics Regulation**

For the assessment of materials in contact with foodstuffs in Europe the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and its last amendment Regulation (EU) 2024/3190 can be employed.

The fully set adhesive may fulfil the migration limits of the above mentioned regulation, as far as the adhesive is concerned.

We expressly point out that with reference to the Union Guidelines and the Union Guidance regarding information within the supply chain, both published in respect to the Plastics Regulation, this regulation does not define *compositional requirements* to printing inks, adhesives and coatings. The Plastics Regulation does apply to plastic layers, even if these layers are bound together with layers of other materials to form a multi-material-multilayer. However, it requires that *specific restrictions* for substances listed in the Union List must be respected in case of a plastic multi-layer material as final product, regardless of how much the different layers contribute to the migration of the substance concerned. Hence, the specific migration limits (SML) of the Plastics Regulation need to be considered also for the monomers used in the adhesive formulation if these substances are regulated in it.

In accordance with article 12 of the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, the overall migration limit (OML) for all substances without any restrictions shall not exceed 10 mg/dm<sup>2</sup> food contact surface. The maximum value for materials for infants and young children is 60 mg/kg food. For many substances specific migration limits (SML) or other restrictions are specified in the Regulation (EU) No 10/2011 and must be respected.

The table below lists only those migratable monomers and starting substances of the hotmelt adhesive which are restricted with specific limits, and the ones which have not been evaluated on European level. All substances, which are listed in the Plastics Regulation but without any SML value, are covered by the compliance with the overall migration and do not require any additional monitoring.

### TECHNOMELT SUPRA 100

FCM no.	CAS no.	Name	SML / Limitation
264 <sup>1)</sup>	000111-66-0	1-Octene	SML = 15 mg/kg
356 <sup>1)</sup>	000592-41-6	1-Hexene	SML = 3 mg/kg
94 <sup>2)</sup>	-----	Waxes, refined (E 905)	

<sup>1)</sup> in traces

<sup>2)</sup> Dual use additive: This additive is chemically identical with a food additive or flavouring, regardless of its purity. Possible food legislation restrictions on substances with E or FL numbers need to be considered.

Regulation (EU) No 10/2011 and its last amendment Regulation (EU) 2024/3190 relate to materials and articles made of plastics, plastic multi-layers or multi-material multi-layers, which are intended to come into contact with foodstuffs. Therefore, the above mentioned monomer list can only be guidance for the examination of the finished product. As the adhesive producer, we cannot ensure that the specific migration limits are respected in the final product. Please consider that the manufacturer of the final packaging carries this responsibility. According to annex V, chapter 2 of the Regulation (EU) No 10/2011, migration testing should be carried out on the finished article under actual conditions of use. For the realization of the migration tests please consider annex III and annex V of the Regulation (EU) No 10/2011.

- **Remark on genotoxic substances**

Regulation (EU) 2020/1245 requires a communication within the supply chain of possible genotoxic substances, if it cannot be ruled out that a migration of more than 0.00015 mg/kg food or food simulant is expected from the final material.

In our opinion, genotoxic substances meet one of the following criteria:

- Substance for which there is a harmonised classification (CLP, Annex VI) as mutagenic
- Substance classified as mutagenic as a result of its REACH registration
- Substance for which there is a regulatory assessment as mutagenic/genotoxic
- Substance that obviously have a strong structural similarity to known mutagens.

The formulation does not contain genotoxic substances that were given to us by our raw material suppliers or that are known based on our own toxicological assessment.

### ***Dual use additives***

Dual use additives are substances that can be used both as additives for food contact materials and as food additives.

Dual use additives, if present, are named in the SML table above or in chapter 'NIAS'.

### ***Bisphenol A, bisphenols and bisphenol derivatives***

Bisphenol A (BPA, CAS no. 80-05-7), bisphenols and bisphenol derivatives are not part of our formulation TECHNOMELT SUPRA 100. They are not present in our raw materials for our product and not released during the application of the product, either. These substances are not added to the finished product. We do not have any reason to expect that these substances are being formed during the manufacturing process. Consequently, we do not check their presence. Therefore, our product complies with Regulation (EU) 2024/3190.

### ***Epoxy Regulation***

TECHNOMELT SUPRA 100 does not contain any epoxy derivatives as part of the formulation, i.e. 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE) and its derivatives, novolac glycidyl ethers (NOGE) and bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE) as mentioned in the Regulation (EC) No 1895/2005. These substances are not added to the finished product. We do not have any reason to expect that these substances are being formed during the manufacturing process. Consequently, we do not check their presence.

### ***Ministerial Decree 21/03/1973 and amendments (Italy)***

The Ministerial Decree 21/03/1973 was released at national level for the evaluation of materials and articles intended to come into contact with foodstuffs.

According to Article 3 of the decree, articles intended to come into contact with foodstuffs have to be composed solely of the substances listed in Annex II under the conditions, limitations and tolerances of use specified in it. In accordance with Article 5 of the DM 21/03/1973 - unless otherwise stated for the individual materials and articles – materials and articles must not transfer their constituents to food products in quantities above 8 mg/dm<sup>2</sup> of the material's or article's surface or 50 mg/kg food (overall migration limit).

For plastics and plastic multilayer article 9 *bis* specifies an overall migration limit of 60 mg/kg food.

Unless otherwise indicated, the restrictions given in our statement with reference to Regulation (EU) No 10/2011 are identical to the ones of DM 21/03/1973 and the information or risk assessments are

also valid for the evaluation of conformity under DM 21/03/1973. This includes the information in the chapter 'NIAS' (non-intentionally added substances).

### **FDA (USA)**

TECHNOMELT SUPRA 100 is a packaging adhesive, which normally under foreseen and intended conditions of use does not come into direct contact with food. This product serves as a bonding of two substrates and the adhesive seam therefore is covered against the foodstuff.

TECHNOMELT SUPRA 100 is in compositional compliance with the Indirect Food Additives regulation 21 CFR 175.105 'Adhesives'.

Paragraph 175.105 of the 21 CFR of the FDA regulation is a specific paragraph for adhesives. This paragraph contains requirements for adhesives followed by a table with substances allowed in adhesive formulations and their specific restrictions.

In addition to the compositional compliance, 21 CFR 175.105 requires either a functional barrier between the adhesive and the filling good or contact of the adhesive with dry foodstuff and the quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice (GMP). If the adhesive has contact with fatty and aqueous foods, the quantity of adhesive that contacts the filling good shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

Thus, 21 CFR 175.105 allows only a limited direct food contact for dry, fatty and aqueous foodstuffs. As the final product – i.e. the whole packaging - must be taken into consideration, the manufacturer of this packaging has to take care that the amount of adhesive in direct food contact should not exceed the limits of good manufacturing practice.

### **Migration tests**

TECHNOMELT SUPRA 100 is a packaging adhesive, which normally under foreseen and intended conditions of use does not come into direct contact with food, as this product serves as a bonding of two substrates and the adhesive seam therefore is covered against the foodstuff. A direct food contact can only occur on the adhesive joint and on the edges. Taking into consideration the demand of article 3 of the Framework Regulation (EC) No 1935/2004, according to which the materials and articles intended to come into contact with food should be manufactured according to good manufacturing practice, we assume that the direct food contact for the above mentioned adhesive should be extremely low.

According to the methods for the "Ministerial corpus of the examination" corresponding to § 64 LFGB and according to the rules of the series of standards EN 1186 overall migration tests for TECHNOMELT SUPRA 100 were carried out. For these tests 50 % (v/v) ethanol was chosen as food simulant during a time period of 10 days at 40 °C in contact with one side of the adhesive film. The value for the overall migration of this adhesive was not detectable, i.e. it was below 1 mg/dm<sup>2</sup>.

A specific test for volatile substances via headspace gas chromatography and FID showed that these are below the maximum permissible value.

According to the results of the migration tests, TECHNOMELT SUPRA 100 may be used safely for the manufacture and closing of foodstuff packaging, especially for gluing fruit and vegetable trays, for sealing folding board boxes, pouches and paper carrier bags, for gluing covering boards and trays as well as for applying drinking straws and bonding spouts to cardboard packaging.

Packaging manufactured with this hotmelt adhesive may stand in direct contact with foodstuffs as far as the adhesive is concerned.

The measurements performed by us for our adhesive do not release the user from the obligation to carry out own investigations on the finished article. It is recommended to check organoleptic influences of the finished food contact material. This sensory analysis can only be performed on the specific foodstuff.

### **NIAS**

Caused by their manufacturing processes, our raw materials and products contain unintentionally introduced substances, so-called NIAS (non-intentionally added substances). From our point of view, these involve either impurities, by-products, decomposition products or reaction products which are technically unavoidable and have to be taken into account for the risk assessment of the final product according to the European Commission.

The NIAS listed below are based on information from our raw material suppliers and/or findings of our own investigations. Substances present in our above named adhesive without intention involve:

- **Salts/Metals**

Packaging manufactured with the adhesive named above can meet the specific migration limits of the substances mentioned in Annex II Table 1 as far as the adhesive is concerned. Salts based on arsenic, cadmium, chromium, lead and mercury are not part of the adhesive's formulation. Recital 13 of the Regulation (EU) 2020/1245 recommends monitoring these metals in the final product in order to exclude any possible contamination that would pose a possible health risk to the final consumer.

Measurements on representative samples of this adhesive group using atomic emission spectrometry (ICP-OES) and plasma mass spectrometry (ICP-MS) have shown that, with the exception of minor amounts of aluminum, the substances with a specific restriction named in Annex II Table 1 were not detected in the adhesive samples (detection limit: 1 mg/kg adhesive).

- **Oligomers**

The formulation of the above mentioned product contains polymeric additives like waxes and hydrogenated hydrocarbon resins listed in the Union List of the Plastics Regulation under FCM 94, FCM 549 and FCM 97. These substances are listed in the positive list of the Plastics Regulation without a restriction.

When polymerizing the above named raw materials, oligomers are formed as part of the molecular weight distribution. When a petition is filed and EFSA evaluates a polymeric additive, information about the molecular weight distribution and the percentage of the molecular weight fraction below 1000 Da is requested, so that the oligomers in the polymeric additive are covered by the evaluation of the whole substance.

TECHNOMELT SUPRA 100 also contains synthetic polymers based on polyolefins whose monomers are listed in the Plastics Regulation. The respective raw materials contain a proportion of oligomers. In a project on the risk assessment of polyolefins performed at the Fraunhofer Institute for Process Engineering and Packaging (IVV) in Freising (Germany) it was found that oligomers with a molecular weight below 1000 Da, located in the polyolefins, represent no concern for the safety of the consumer.

- **Decomposition products**

For the protection of our raw materials and finished goods the use of stabilizers is absolutely necessary. The role of these substances is to protect the polymeric formulation components from oxidative degradation initiated by light and / or heat during the production, storage and processing stage.

The formulation of the above mentioned product contains the stabilizer phosphorous acid, tris(2,4-di-tert-butylphenyl)ester (CAS no. 31570-04-4). This substance is listed in the Union List of the Plastics Regulation under FCM 671 without an SML value. During its oxidation the following substances are formed:

- tris(2,4-di-tert-butylphenyl) phosphate (CAS no. 95906-11-9, SML = 0.05 mg/kg food)
- 2,4-di-tert-butylphenol (CAS no. 96-76-4, SML = 0.05 mg/kg food)
- 4-tert-butylphenol (CAS no. 98-54-4, FCM 186, SML = 0.05 mg/kg food).

The formulation of the above mentioned product contains the stabilizer pentaerythritol-tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate] (CAS no. 6683-19-8). This substance is listed in the Union List of the Plastics Regulation under FCM 496 without an SML value. The following substances are known as possible decomposition products:

- 2,6-di-tert-butyl-p-benzoquinone (CAS no. 719-22-2, SML = 0.54 mg/kg food)
- 3,5-di-tert-butyl-4-hydroxystyrene (CAS no. 52858-87-4, SML = 0.54 mg/kg food)
- 3,5-di-tert-butyl-4-hydroxybenzaldehyde (CAS no. 1620-98-0, SML = 0.09 mg/kg food)
- 3,5-di-tert-butyl-4-hydroxyacetophenon (CAS no. 14035-33-7, SML = 0.09 mg/kg food)
- 7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione (CAS no. 82304-66-3, SML = 0.09 mg/kg food)
- methyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS no. 6386-38-5, SML (T) =

- 0.5 mg/kg food)<sup>1)</sup>
- 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propanoic acid (CAS no. 20170-32-5, SML (T) = 0.5 mg/kg food)<sup>1)</sup>
- ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propanoate (CAS no. 36294-24-3, SML (T) = 0.5 mg/kg food)<sup>1)</sup>
- 2,6-di-tert-butyl-4-ethylphenol (CAS no. 4130-42-1, FCM 477, SML = 4.8 mg/kg food).

<sup>1)</sup> valid for the sum of all three substances

Unless explicitly mentioned (indicated by FCM number), the above listed SML values of the decomposition products are based on our own toxicological assessments, which are available upon request.

For alcohol-containing foods and in case of migration tests carried out in ethanolic food simulants formation of further NIAS has to be considered in addition to the decomposition products mentioned above. Additional substances can be generated by trans-/esterification during the performance of the test or by reaction with the foodstuff.

### ***Mineral oil and mineral oil components***

Recent studies on the subject of 'mineral oil' show that the transition from mineral oil hydrocarbons (MOH) into food can cause health concerns for consumers. According to an EFSA study from 2012, updated in July 2023 ("Update of the risk assessment of mineral oil hydrocarbons in food", EFSA 2023), there are numerous sources to contaminate food with mineral oil hydrocarbons. Not only the food packaging can contain mineral oil components, but food can also be contaminated with mineral oil components prior to packaging, due to the transport of some food ingredients in mineral oil-soaked jute bags or the use of mineral oil-containing lubricants in the production of food.

Extensive studies of the official food control authority of the Canton Zürich in Switzerland show that the main mineral oil contamination source in food packaging is the use of recycled paper which, due to its production, may contain a high proportion of oils from the newspaper printing inks. A food contamination with mineral oil components from adhesives can only be very low due to the small proportion of this component of the total package.

As the research shows, the contamination of food by MOH occurs less as a result of migration but rather because of mass transfer through the gas phase, i.e. based on evaporation and condensation. Therefore, especially low molecular substances with a chain length of up to 25 carbon atoms are relevant for this process.

TECHNOMELT SUPRA 100 is a hotmelt adhesive based on synthetic polymers, waxes and hydrocarbon resins.

TECHNOMELT SUPRA 100 is a non-reactive product. Therefore, we assume that during the melting, application as well as the subsequent setting of the adhesive, no further substances are formed that

could possibly contribute to MOH fractions in the analytical determination of mineral oils or mineral oil constituents.

- **MOSH / MOAH**

Hydrocarbons from mineral oil (MOH) are divided into two groups: MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons). Typical examples of these hydrocarbons can be found in the EFSA studies from 2012 and 2023. According to the latest EFSA assessment, exposure to MOSH is not a cause for concern for human health. In contrast, especially the MOAH group is of toxicological concern, as the presence of carcinogenic substances is suspected in the high aromatic content. According to current knowledge, MOAH compounds with three or more ring systems appear to be particularly critical. In the absence of relieving toxicological data a corresponding high health risk must be assumed and products containing MOAH should therefore not get into direct contact with food. If nonetheless applied, it should always be taken care of having a sufficient functional barrier.

Based on the latest studies on mineral oil compounds, the member states of the European Union have decided that food will be withdrawn from the market or recalled if the sum of MOAH substances in the food reaches or exceeds the following maximum quantification limits (LOQ):

- 0.5 mg/kg for dry foods with a low fat/oil content ( $\leq 4\%$  fat/oil)
- 1 mg/kg for foods with a higher fat/oil content ( $> 4\%$  fat/oil)

- **Oil**

The product neither contains oil as part of the formulation, nor mineral oil which is obtained from hydrocarbons of petroleum origin and therefore also no MOSH- / MOAH-components derived from mineral oil.

- **POSH**

Besides MOSH and MOAH, also the so-called POSH (Polyolefin Oligomeric Saturated Hydrocarbons) as oligomeric by-products of polyolefins contribute to a possible contamination of food. By analytical determination, it is difficult to distinguish between MOSH and POSH. Thus, in examinations POSH can be detected as a mineral oil component by mistake, although POSH substances have no origin in a mineral oil fraction.

TECHNOMELT SUPRA 100 contains synthetic polymers based on polyolefins.

- **Oligomers of waxes**

TECHNOMELT SUPRA 100 contains waxes which represent defined substance groups by means of detailed specifications and toxicological examinations. These are listed in the positive list of the Plastics Regulation, the so-called Union List, as FCM 94 and FCM 549 and hence are permitted for food

contact. In addition, waxes with FCM 94 are authorized in Europe as food additives under the E number 905.

This classification of FCM 94 is confirmed by the highest European Food Safety Authority (EFSA) in its publication dated 06.06.2012, updated on 28.08.2013 (Scientific Opinion on Mineral Oil Hydrocarbons in Food).

These raw materials contain oligomers as a mixture of linear and branched saturated alkanes which can be analytically detected in the MOSH fraction.

- ***Oligomers from hydrocarbon resins and modified natural resins***

Besides MOSH, MOAH and POSH, also oligomers from hydrocarbon resins and modified natural resins might contribute to a possible contamination of food. It is known that the low-molecular constituents of synthetic hydrocarbon resins and modified natural resins contribute to the MOSH- or MOAH-fraction in the analytical examinations. Thus, these substances can be interpreted as mineral oil components by mistake.

TECHNOMELT SUPRA 100 contains synthetic hydrocarbon resins.

The petroleum-based hydrogenated hydrocarbon resins in TECHNOMELT SUPRA 100 are listed in the positive list of the Plastics Regulation under FCM 97 without a restriction and therefore not named in the SML table.

### ***FEICA Guideline for Good Manufacturing Practice***

#### ***FEICA Guidance for a food contact status declaration for adhesives***

Our food contact statements are based on the recommendations of the FEICA-Guidance Paper 'FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in reference to Regulation (EU) No 2023/2006' dated 1<sup>st</sup> March 2015. Please see our chapter 'GMP Regulation' for detailed information.

In our food contact statements we follow the FEICA-Guidance Paper 'Guidance for a food contact status declaration for adhesives' dated 28<sup>th</sup> March 2022.

### ***TKPV – Technical Briefing Notes***

When selecting our raw materials, in the production of our adhesives and when setting up our food contact statements we follow the following guidelines of the German Adhesives Association IVK (Industrieverband Klebstoffe e.V.):

- TKPV 1 Guideline – Food legislation status of adhesives used in the manufacturing of materials and articles intended to come into contact with food (German Version: March 2016)
- TKPV 2 Guideline – Food legislation status of adhesive raw materials for adhesives used in the manufacturing of materials and articles intended to come into contact with food (German Version: March 2016)

- TKPV 3 Guideline – „Good manufacturing practice“ for adhesives used in the manufacturing of materials and articles intended to come into contact with food (German Version: June 2015)
- TKPV 4 Guideline – Hygiene during production of adhesives used in the manufacturing of materials and articles intended to come into contact with food (German Version: March 2016)

The assessment in this document does not generally release the user of the above mentioned product from the obligation to conduct own investigations on the finished article. Our risk assessment loses its validity in case our product is not used as recommended by the technical datasheet and / or mixed with another product before the application. The information given in this food contact statement is solely supplied for internal safety evaluation.

If you have any further questions, please do not hesitate to contact us again. Please also visit our knowledge platform [www.henkel.com/foodsafety](http://www.henkel.com/foodsafety) which offers many food safe packaging related information such as white papers, webinars and videos.

Kind regards,

**Henkel AG & Co. KGaA**

A handwritten signature in blue ink that reads "Valentina Zanni".

Valentina Zanni

A handwritten signature in blue ink that reads "M. Tönnießen".

Dr. Monika Tönnießen

Head of Food Safety Compliance – Global Food Safety