Henkel AG & Co. KGaA, 40191 Düsseldorf, Deutschland

To all customers

Datum / Date	19.11.2025	Abteilung / Dept.	Product Safety & Regulatory Affairs
Ihre Nachricht / Your message		Telefon / Phone	+ 49-211-797-6880
		Telefax / Fax	+ 49-211-798-16880
		E-Mail / E-mail	Monika.Toenniessen@Henkel.com

Dear Sir or Madam,

Referring to your request concerning the food contact status we can declare the following for our European[1] 3D printing resin LOCTITE 3D IND3785 (SDS no.: 851373):

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 dispensing tube, which moreover represents only a small part of the total machine, is not the right approach to evaluate compliance with the respective food contact regulations. Due to the wide range and diversity of materials (plastics, metals etc.) we cannot test the special conditions of each customer. The organoleptic characteristics can be monitored only on the treated foodstuff and therefore fall under the responsibility of the resin user.

Henkel is unable to state compliance to Framework Regulation (EC) No 1935/2004 as the 3D printing resin supplied is not used as a food contact material in its own right. The product is intended to function as part of a finished food contact article.

[1] EU, Switzerland, Norway, UK

Nonetheless, Henkel has conducted a risk assessment of the 3D printing resin (see details in the chapters below) and confirms that the product is suitable for use in food contact articles. When applied in accordance with our recommendations given in the technical datasheet and according to good manufacturing practice the product can support the final article to meet the requirements of Article 3 of the Framework Regulation (EC) No 1935/2004.
We remind our customers that they should make the evaluation of their finished article, and we provide the necessary information regarding our product to enable them to do so.

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 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.

Following article 16 of the Framework Regulation we refer in our assessment to the specific measures on plastic materials and articles intended to come into contact with foodstuffs, Regulation (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 1st 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 or ISO 13485 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 contact application. 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) 2025/351 can be employed.

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

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^2 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 acrylic resin which are restricted with specific limits, and the ones which have not been evaluated on European level. In the absence of a listing in the Union List of Regulation (EU) No 10/2011, article 19 of the Plastics Regulation allows an own risk assessement in accordance with internationally recognized scientific principles. 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.

LOCTITE 3D IND3785

FCM no.	CAS no.	Name	SML / Limitation
-----[1), 2)]	072869-86-4	7,7,9(or7,9,9)-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
-----[1), 3)]	052408-84-1	Tripropylene glycol triacrylate 1-6.5 PO	
-----[4)]	162881-26-7	Phenyl bis (2,4,6-trimethylbenzoyl)-phosphine oxide	
-----[1), 3)]	000868-77-9	2-Hydroxyethyl methacrylate	
----[1), 5), 6), 7)]	000150-76-5	4-Methoxyphenol (FL No. 04.077)	
295[6)]	000123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
315[5), 6)]	000128-37-0	2,6-Di-tert-butyl-p-cresol (BHT, E 321)	SML = 3 mg/kg
295[5)]	000123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
129	000075-21-8	Ethylene oxide	SML = not detectable (DL = 0.01 mg/kg) 1 mg/kg in final product
135	00075-56-9	Propylene oxide	SML = not detectable (DL = 0.01 mg/kg) 1 mg/kg in final product

1) not listed in the Plastics Regulation
2) recommended limit value of SML = 0.05 mg/kg determined by own toxicological assessment
3) recommended limit value of SML = 5 mg/kg determined by own toxicological assessment
4) not listed in the Plastics Regulation but in Annex 10 to SR 817.023.21 as photo initiator for printing inks with an SML of 3.3 mg/kg, based on our own toxicological assessment we recommend a value of SML = 0.05 mg/kg
5) 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.

6) stabilizer

7) recommended limit value of SML = 0.18 mg/kg determined by own toxicological assessment

Following the Plastics Regulation, recital 27 of the preamble and article 13, paragraph 3 prescribes a migration limit of 0.01 mg/kg for non-authorized substances that are used behind a plastic functional barrier.

Regulation (EU) No 10/2011 and its last amendment Regulation (EU) 2025/351 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 resin producer, we cannot ensure that the specific migration limits are respected in the final product. Please consider that the manufacturer of the final food contact article 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.

Since we cannot estimate the possible migration for the final product of each customer due to the large variety of different packaging materials, manufacturing processes and filling conditions, we list below all genotoxic substances that were given to us by our raw material suppliers or that are known based on our own toxicological assessment. Regulation (EU) 2020/1245 provides a generic limit value of 0.00015 mg/kg food or food simulant for all genotoxic substances for which no specific toxicological data are available. A substance-specific higher threshold value can be set for those substances that have been investigated and for which data are available. The resulting specific restrictions in the various legislations are communicated in the table below and can be used for the risk assessment of the respective substance.

CAS no.	Name	SML / Limitation	Maximum concentration*
000075-21-8	Ethylene oxide	SML = not detectable (DL = 0.01 mg/kg)[1)] 1 mg/kg in final product[1)]	unknown
000487-68-3	2,4,6-Trimethyl-benzaldehyde		See footnote[2)]

***** maximum concentration in the product as delivered without taking into account possible losses during production and processing

1) restriction of the Plastics Regulation

2) Based on results of our own migration tests we calculated the tolerable food contact area to 3D-printing resin depending on the contact time so that the generic limit of 0.15 µg/person/day is respected:

Contact time	Detected migration [ng/cm²]	Tolerable contact area [cm²]*
5 minutes	3	50.00
1 hour	29	5.17
24 hours	191	0.79

* Depending on the contact time, the amount of food consumed by one person per day should not be in contact with more than the indicated 3D printing resin surface

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.

Bisphenol A, bisphenols and bisphenol derivatives

Bisphenol A (BPA, CAS no. 80-05-7), bisphenols and bisphenol derivatives are not part of our formulation LOCTITE 3D IND3785. 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

LOCTITE 3D IND3785 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.

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 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).

- ***Decomposition products from stabilizers***

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 decomposition initiated by light and / or heat during the production, storage and processing stage. The presence of decomposition products resulting from stabilizers is known to analytical institutes.

The formulation of the above named product contains various raw materials which are stabilized with 4-methoxyphenol, 1,4-dihydroxybenzene or 2,6-di-tert-butyl-p-cresol. These stabilizers are named in the SML table above and marked as such. They can build NIAS by degradation during the shelf life of our product.

The formulation of the above mentioned product contains the stabilizer 2,6-di-tert-butyl-p-cresol (BHT, CAS no. 128-37-0). This substance is listed in the Union List of the Plastics Regulation under FCM 315 with an SML value. In addition, this stabilizer is approved as a food additive with E 321 in Europe. The following substances are known as possible decomposition products:

- 3,5-di-tert-butyl-4-hydroxybenzaldehyde (CAS no. 1620-98-0, SML = 0.09 mg/kg food)
- 2,6-di-tert-butyl-2,5-cyclohexadiene-1,4-dione (CAS no. 719-22-2, SML = 0.54 mg/kg food)
- 2,6-di-tert-butyl-4-methylene-2,5-cyclohexadien-1-one (CAS no. 2607-52-5, SML = 0.54 mg/kg food)
- 2,6-di-tert-butyl-4-phenol (CAS no. 128-39-2, SML = 1 mg/kg food)
- 4,4-ethylenebis(2,6-di-tert-butylphenol) (CAS no. 1516-94-5, SML = 0.09 mg/kg food)
- 4,4-ethanediylidenebis(2,6-di-tert-butyl-2,5-cyclohexadien-1-one) (CAS no. 809-73-4, SML = 0.54 mg/kg food)
- 2,6-di-tert-butyl-4-hydroxy-4-methyl-2,5-cyclohexadien-1-one (CAS no. 10396-80-2, SML = 0.09 mg/kg food).

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.

- ***Decomposition products from photoinitiator***

For the curing of the acrylates LOCTITE 3D IND3785 contains the photo initiator phenyl bis (2,4,6-trimethylbenzoyl)-phosphine oxide (CAS no. 162881-26-7). It is well known that this photo initiator releases breakdown products during the photolysis. These decomposition products are 2,4,6-trimethyl-benzaldehyde (CAS no. 487-68-3), 2,4,6-trimethylbenzoic acid (CAS no. 480-63-7) and bis(2,4,6-trimethylphenyl)ethane-1,2-dione.

- ***Decomposition products from acrylates***

LOCTITE 3D IND3785 contains an acrylate copolymer which forms the decomposition products acrylic acid (CAS no. 79-10-7) and methacrylic acid (CAS no. 79-41-4) as NIAS. Both acids are listed in the Plastics Regulation under FCM no. 147 or FCM no. 150 each with SML (T) = 6 mg/kg. We assume that this NIAS evaporates during the curing process.

- ***Impurities***

Our product LOCTITE 3D IND3785 is an acrylic resin. It may contain traces of the solvent toluene (CAS no. 108-88-3) as an impurity present in one of our raw materials. Toluene is not listed in the Plastics Regulation but in the Spanish Real Decreto 847/2011 with an SML value of 1.2 mg/kg. Ethyl acetate is listed in the Plastics Regulation without restriction.

Since solvents are regarded as aids to polymerization, they are normally not included in the Union List of the Plastics Regulation. The legislator assumes that the solvents are used in the manufacture of plastics to create a suitable reaction environment but are removed in the subsequent manufacturing process as they are usually volatile.

LOCTITE 3D IND3785 contains the photoinitiator phenyl bis (2,4,6-trimethylbenzoyl)-phosphine oxide (CAS no. 162881-26-7). This substance contians a low amount of 2,3,4,6-tetramethylbenzoyl-2,4,6-trimethylbenzoyl)-phenylphosphine oxide as technically unavoidable impurity.

LOCTITE 3D IND3785 contains tripropylene glycol triacrylate 1-6.5 PO as starting component. This raw material contains ethylene/propylene glycol diacrylate as technically unavoidable impurity. Based on our own toxicological assessment we recommend a value of SML = 0.05 mg/kg for this impurity.

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 which offers many food safe packaging related information such as white papers, webinars and videos.

Kind regards,
Henkel AG & Co. KGaA

Corina Bongers
Specialist - Global Food Safety

Dr. Monika Tönnießen
Head of Food Safety Compliance – Global Food Safety