

Certificate

Food regulatory assessment of the adhesive "Loctite® 9480" for applications with incidental food contact

Client: Henkel AG & Co. KGaA

85748 Garching, Germany

Order: PA/4622/14 and PA/4054/15

Sample: Adhesive system "Loctite® 9480"

Application range of "Loctite® 9480":

The two part epoxy-based adhesive "Loctite® 9480" is intended be used as a component in food contact applications. Typically, "Loctite® 9480" shall be used to assemble pieces of metal and / or plastics in food processing and packaging machines as well as in household applications like mixers, pasta machines or microwave ovens. For these applications the adhesive is generally located between the adherent materials, therefore direct food contact of the adhesive is not intended, but may occur incidentally via the edge parts (bond line) of the applied adhesive.

Food regulatory status of the components used for "Loctite® 9480"

The food regulatory status of the components used for the epoxy-based adhesive "Loctite® 9480" was assessed according to the European legislation for food contact materials, e.g. Plastics Regulation (EU) No 10/2011 (Fraunhofer IVV test report PA/4622/14 dated 19.01.2014). For that purpose, the formulation of the adhesive system "Loctite® 9480" was disclosed to Fraunhofer IVV by Henkel Slovensko spol. s.r.o on the basis of confidentiality.

Assessment of the possible migration from "Loctite® 9480":

Based on the formulation check several components were identified that are subjected to specific migration limits (SML) or to residual limits (QM), respectively, according to the European Plastics Regulation (EU) No 10/2011 (last amendment by Regulation (EU) No 2015/174).

For the evaluation of the migration potential from the epoxy-based adhesive "Loctite® 9480" the residual contents of these components in the cured adhesive were determined by extraction tests. For the evaluation it was presumed that the total concentration found in the cured adhesive is transferred into the food (total mass transfer), which is an extremely conservative assumption (Fraunhofer IVV test report PA/4054/15 parts 1 to 4 dated 27.5.2015).

In addition, the intended application range was also considered for the evaluation of the possible migration. For the intended application range of "Loctite® 9480" only a very small surface of the adhesive will come into contact with food, as the adhesive is located between the adherents. The adherents (e.g. plastics, metals) can be considered as functional barriers, so that only perimetral (edge) parts of the bond line of the adhesive layer may come in direct contact with food.

Based on the extraction studies and taking into account a maximum reasonable total food contact area of $0.1~dm^2$ for the intended applications of "Loctite® 9480" (corresponding to an adhesive line of 2 m at a bond line thickness of 500 µm), the affected specific migration limits will be respected in contact of $0.1~dm^2$ adhesive with more than 7.8 kg of food (worst case scenario). However, the migration of compounds subjected to restrictions will be clearly lower at the intended applications than the values derived from total extraction.

Additionally, for the intended application of the adhesive in food processing and packaging machines repeated use conditions as well as very short contact times with large volumes of food can be assumed. For the use of the adhesive system as component in household applications (e.g. mixers, pasta machines or microwave ovens) the transfer of components from the adhesive into food will foreseeably take place only incidentally at short contact times.

Summarising assessment:

Based on the above considerations, it can be concluded that the specific migration limits and residual limits in effect for the components of the epoxy-based adhesive "Loctite® 9480" will be respected for the use of "Loctite® 9480" in any kind of food processing and packaging machines (e.g. for meat, fish, poultry) as well as in household applications (e.g. mixers, pasta machines or microwave ovens) with only incidental food contact under all contact conditions.

Therefore, we come to the conclusion that the use of the epoxy-based adhesive "Loctite® 9480" for the described applications with incidental food contact under normal or foreseeable conditions of use, will not lead to the transfer of the investigated constituents into food in quantities which could endanger human health following the requirement of Article 3 (1a) of the EU Framework Regulation No 1935/2004.

Fraunhofer Institute Process Engineering and Packaging

Dr. Diana Kemmer

(Dep. Head of Migration Laboratory)

Freising, 02.07.2015

Carina Gehring

(Food Chemist)