

STATEMENT

tesa® 4190

For the European market, the EU Framework Directive 1935/2004 from 27-10-2004 applies for "materials and objects, which are intended to come into contact with food". This directive defines the general conditions concerning the suitability of materials and objects, which as a finished product are intended to come into contact with food. Furthermore, this framework regulation refers to specific rules for individual food-relevant products and/or materials, such as plastics, ceramics, regenerated cellulose, etc., and in Annex I, among other things, it announces a regulation for adhesives (however, not for tapes/labels). This means that presently there is no specific regulation for adhesive tapes/labels on a European level.

In this respect - in the absence of adhesive-specific regulations - no legally binding declaration of conformity must be issued for the purposes of Article 16 of the European Framework Directive 1935/2004!

However, Article 6 of the Framework Directive 1935/2004 allows the application of national rules, provided that they are compatible with the contractual provisions. The recommendations of the German Plastics Commission of the Federal Institute for Risk Assessment ("Kunststoff-Kommission des Bundesamtes für Risikobewertung" / BfR - formerly BGVV or BGA) fulfill the status of national rules and thus can be used - in combination with the EU regulations, such as the EU Plastics Directive 2011/10/EC - for food law assessment of tapes/labels.

The a.m. tesa® tape - delivered by tesa SE – is used in the food packing industry.

tesa® 4190 is used inter alia as an carton sealing tape in the food packaging industry.

This area of application has been changed in accordance with the provisions of the Food and Feed Code ("Lebens- und Futtermittelgesetzbuch" - LFGB), the EU Regulations 2011/10/EC, 1935/2004/EC and the relevant provisions of the Consumer Goods Ordinance in the version published on December 23, 1997 (BGBl. 1998 I p.5), last amended by Article 1 of the regulation from June 24, 2013 (BGBl. I, p. 1682).

With a proper use of the a.m. tesa tape, however, a migration of the adhesive or its individual ingredients into the food is unlikely, since the tape is used as an carton sealing tape and don't come in contact with the food.

Therefore, the use of the tesa tape in the food industry - in accordance with §8 of the Consumer Goods Ordinance [Bedarfsgegenständeverordnung] - is considered safe according to §31 sec. 1 of the LFGB. And therefore, the provisions of the Consumer Goods Ordinance (§5) do not apply for the processing of the label.

Special notice:

tesa® tapes can be used for indirect food contact only!!

The implementation of the application is the responsibility of the user, who needs to make sure that no transfer of adhesive ingredients to food, drugs or other items that come into direct contact takes place. The migration behavior of adhesive constituents can potentially vary, and may - among others - depend on the conditions of application. Moreover, the barrier function of a separation layer (for example, a primary package or a constructive component), which should prevent the penetration of adhesive components in the contents or the direct contact with sensitive objects, can be impaired. All these (potential) influencing factors should be considered and - when in doubt - investigated by a specialized institution.

All raw materials used for the production of the tesa tape is listed in CFR 21 section 175.105.

Since the a.m. tesa tape is a technical product, which is not produced specifically for the food industry, the production process is also not subject to the provisions of the LFGB (German Food and Feed Code). This means that the required GMP conditions (Good Manufacturing Process) do not apply to the manufacture.

Quality management

Product safety / EU safety advisor dangerous goods

A handwritten signature in black ink, appearing to be "Dirk Lamm".

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