

Henkel AG & Co. KGaA, 40191 Düsseldorf, Deutschland

To all customers

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Dear Sir or Madam,

Referring to your request concerning the food contact status we can declare the following for our adhesive AQUENCE FB 7362 known as Adhesin A 7362:

- **Framework regulation**

The European framework directive 89/109/EEC, replaced on 27th October 2004 by the regulation (EC) No 1935/2004 sets out the general rules for materials and articles intended to come into contact with food on an European level.

Under the European framework directive 89/109/EEC, specific rules for adhesives in food applications have up to now not been enacted. In addition be aware that 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 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 manufacturer of the packaging has to take care that no constituent transfers to food in such quantities that there is a risk for the final consumer. 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

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(different foils, inks etc.) we can not test the special conditions of each customer. Most specifically, the organoleptic characteristics can be monitored only on the packaged foodstuff and therefore fall under the responsibility of our customer.

In reference to article 17 of the framework 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.

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 for plastic materials and articles intended to come into contact with foodstuffs (EU) No 10/2011, replacing the plastic directive and its amendments on 1st May 2011.

- **GMP regulation**

Article 3 of the framework regulation requires that materials and articles intended to come into contact with food shall be manufactured in compliance with good manufacturing practice. As our production sites are accredited to ISO 9001 we have established an efficient quality assurance and quality control system. By means of an HACCP analysis, a hazard identification and a risk assessment were executed for the manufacturing sites in which we produce adhesives for food packagings. 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 adhesive is manufactured in compliance with the regulation (EC) No 2023/2006 on good manufacturing practice (GMP regulation).

- **Plastic regulation**

For the assessment of materials in contact with foodstuffs in Europe the plastic regulation (EU) No 10/2011 and its last amendment regulation (EU) No 1183/2012 can be employed.

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

According to paragraph 6 of the plastic regulation's preamble and article 2, paragraph 2, this regulation specifically is not valid for adhesives and coatings, but only applies to the plastic layers in multi-material multi-layers and does therefore not regulate monomers and other components specially used for adhesives. Certainly an adhesive in indirect food contact can be considered as a part of a laminated plastic packaging. In this case monomers with specific migration limits used in the formulation of the adhesive have to be consulted.

In accordance with article 12 of the regulation (EU) No 10/2011 for 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/dm² 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.

AQUENCE FB 7362 is a plasticized dispersion adhesive mainly based on synthetic polymers.

As the plastic regulation is a regulation for plastic materials based on different monomers the raw materials used can only be found in this regulation when the adhesive is build up of monomers by the polymerization reaction. Therefore, preservatives and initiators, that are absolutely needed to manufacture these aqueous systems, cannot always be found in the plastic regulation's list.

The table below lists those monomers and other substances, which may contribute to the migration, for which the plastic regulation (EU) No 10/2011 mentions specific limits or that are subject to other restrictions.

In this table only substances are listed, which are subject to restrictions. All substances, which are listed in the plastic regulation but without any SML value, are covered by the compliance with the overall migration and do not require any additional monitoring.

AQUENCE FB 7362 (plasticized)

FCM no.	CAS no.	Name	SML / Limitation
231	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg
128 ¹⁾	000075-07-0	Acetaldehyde	SML (T) = 6 mg/kg
98 ¹⁾	000050-00-0	Formaldehyde	SML (T) = 15 mg/kg
451	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0.5 mg/kg
147	000074-85-1	Acrylic acid	SML(T) = 6 mg/kg
799	-----	Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	SML = 1.8 mg/kg
334	000151-56-4	Etthyleneimine	SML = ND
----- ²⁾	002634-33-5	1,2-Benzisothiazolin-3-one	SML = 0.5 mg/kg
----- ³⁾	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	max 0.003 mg/dm ² in dispersion film
----- ⁴⁾	000079-20-9	Methyl acetate (FL Nr. 09.023)	
115 ⁴⁾	000064-19-7	Acetic acid (as sodium salt, E 262)	
509 ⁴⁾	007664-38-2	Phosphoric acid (as sodium salt, E 339)	
21 ⁴⁾	-----	Carbonic acid (as sodium salt, E 500)	
----- ⁵⁾	000120-55-8	Diethyleneglycol dibenzoate	

AQUENCE FB 7362 (plasticized, continuation)

FCM no.	CAS no.	Name	SML / Limitation
---- ⁵⁾	027138-31-4	Dipropyleneglycol dibenzoate	
---- ⁵⁾	000120-56-9	Triethyleneglycol dibenzoate	

1) In traces as by-products of the polymerization.

2) EFSA opinion SDS EFSA/AFC/FCM 605-Rev.IIB/37520 from August 2007

3) Not listed in the plastic regulation but in the XIV. BfR recommendation

4) This additive is chemically identical with a food additive or flavouring, regardless of its purity. Food legislation restrictions on substances with E or FL numbers need to be considered.

5) Not listed in the plastic regulation but in FDA 175.105.

For non-authorized substances named in the table above which are used behind a plastic functional barrier, paragraph 27 of the plastic regulation's preamble and article 13, paragraph 3 of the regulation prescribe a migration limit of 0.01 mg/kg.

Regulation (EU) No 10/2011 and its last amendment regulation (EU) No 1183/2012 relate to materials and articles made of plastic, plastic multi-layers or multi-material multi-layers, which are intended to come into contact with foodstuffs in their finished state. Therefore the above mentioned monomer lists can only be guidance for the examination of the finished product. As the adhesive producer we can not 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.

- **Dual use**

Dual use substances, if present, are named in the table above.

- **FDA**

AQUENCE FB 7362 is in compositional compliance with the regulations of FDA 175.105 for indirect food contact.

Paragraph 175.105 of the 21 CFR of the FDA regulation is a specific paragraph for adhesives. This paragraph is subdivided into several sections, which contain requirements for adhesives followed by a table with substances, which are allowed to be used in adhesive formulation and with specific restrictions. Our adhesive composition complies with FDA 175.105, when we use only raw materials, which are permitted in this paragraph.

Additionally to the compositional compliance FDA 175.105 requires a functional barrier between the adhesive and the filling good. Incidental 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 incidental 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 FDA 175.105 allows only a limited direct food contact for dry, fatty and aqueous foodstuffs. As the final product – that is 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.

AQUENCE FB 7362 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 of the packaging. Taking into consideration the demand of article 3 of the European 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 mentioned adhesives should be extremely low.

- **BfR**

AQUENCE FB 7362 is a plasticized adhesive and can therefore not comply with the requirements of the XIV. BfR recommendation as this recommendation is valid only for plasticizer-free dispersions. The plasticizer used in AQUENCE FB 7362 is not a phthalate plasticizer.

The information given in this food contact statement is solely supplied for internal safety evaluation. The information may contain trade secrets and must be treated strictly confidential; it must not be disclosed or made accessible to third parties.

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If you have any further questions, please do not hesitate to contact us again.

Kind regards,

Henkel AG & Co. KGaA



Dr. Dario Cavalli



Dr. Monika Tönniesen