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To all customers

Datum / Date	25.11.2018	Abteilung / Dept.	PD Dispersion Technologies
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Dear Sir or Madam,

Referring to your request concerning food contact status, we can declare the following for our European[1] adhesive AQUENCE BG 9040 LM (SDS no.: 457942):

Framework Regulation

The European 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 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 (different foils, inks etc.) we

[1] EU, Switzerland, Norway

cannot 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 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 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 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 certified 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).

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) 2018/831 can be employed.

The fully dried 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/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 BG 9040 LM is a dispersion adhesive based on synthetic polymers.

As the Plastics 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 Plastics Regulation's list.

The table below lists only those migratable monomers and starting substances of the 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.

Taking into consideration a max. amount of 1 g wet adhesive / kg foodstuff, i.e. 1 g / 6 dm² food packaging (8 g dry adhesive / m²) we have calculated whether or not the migrant migrates into the foodstuff under worst case conditions, i.e. assuming that the whole quantity migrates. The results of these worst case calculations are named in the last column of the SML table.

AQUENCE BG 9040 LM

FCM no.	CAS no.	Name	SML / Limitation	Specific migration test necessary
231	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg	No
21[1)]	-----	Carbonic acid (as sodium salt, E 500)		see remark[1)]
107[1)]	000057-13-6	Urea (E 927B)		see remark[1)]
-----[2), 3)]	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	max 0.003 mg/dm² in dispersion film	No
-----[2), 3)]	013590-97-1	Dodecylguanidine hydrochloride	max 0.03 %	No
-----[2), 4)]	002634-33-5	1,2-Benzisothiazolin-3-one	SML = 0.5 mg/kg	No
451[2)]	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0.5 mg/kg	No
-----[2), 3)]	003586-55-8	1,6-Dihydroxy-2,5-dioxahexane	max 29 µg/dm²	Yes[5)]

[1] 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.
[2] Preservative (Biocide)
[3] Not listed in the Plastics Regulation but in the XIV. BfR recommendation
[4] EFSA opinion SDS EFSA/AFC/FCM 605-Rev.IIB/37520 from August 2007
[5] This worst case calculation is made under the estimation that the substance does not at all decompose in aqueous medium, which is not the case. Additionally, it has to be considered, that the equilibrium will be shifted on the side of the decomposition products (ethylene glycol and formaldehyde, see chapter NIAS) during the drying process, so that finally most of the substance is decomposed and the BfR restriction can be respected in the final product.

All SML values marked with 'No' in the last column of the table are covered by the worst case calculation and are not exceeded under the above mentioned conditions. Therefore, a specific monitoring is not required.

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

However, Regulation (EU) No 10/2011 only applies to plastics and plastic layers in a multi-material multi-layer material (recital 6 of the preamble). In the absence of a listing in the Union List of the Regulation (EU) No 10/2011, other regulations and provisions may be used to derive an evaluation for a chemical substance present in an adhesive (article 2, paragraph 3 of Regulation (EU) No 10/2011). In the table above, we indicate all restrictions mentioned in the Union List but also from other sources.

For materials not evaluated in any EU or national regulation or provision, we recommend to apply a 10 ppb migration limit per substance as proposed in the Regulation (EU) No 10/2011 for non-CMR compounds for which no toxicological reference value is available.

Regulation (EU) No 10/2011 and its last amendment Regulation (EU) 2018/831 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 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 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.

Dual use

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

Epoxy Regulation

AQUENCE BG 9040 LM does not contain any epoxy derivatives as part of its formulation, i.e. BADGE and its derivatives, NOGE and BFDGE as mentioned in the European 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.

BfR (Germany)

The BfR recommendations deal with plastics and other high polymers used for commodities, corresponding to the requirements of § 64 of the LFGB (Foodstuffs and Commodities Act). All plastics, for which the monomers and additives are already regulated in the scope of the Regulation (EU) No 10/2011, are no longer mentioned in the revised version of the BfR recommendations and are covered by the Regulation (EU) No 10/2011.

The components of AQUENCE BG 9040 LM comply with the XIV. BfR recommendation for direct food contact.

FDA (USA)

AQUENCE BG 9040 LM 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.

AQUENCE BG 9040 LM 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 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, 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.

NIAS

Caused by their manufacturing processes our raw materials can contain impurities which we unintentionally bring into our adhesive formulations. In addition, technically unavoidable impurities or by-products can be formed during the manufacturing of our products which need to be considered in the risk assessment of the final product. Substances brought into our above named product without intention, so-called NIAS (non-intentionally added substances) involve:

- ***By-products***

It is well-known that during the polymerisation of vinyl acetate the formation of formaldehyde (CAS no. 50-00-0) and acetaldehyde (CAS no. 75-07-0) as polymerisation by-products is technically unavoidable. Each substance is listed in the Union List of the Plastics Regulation with an SML value: Formaldehyde (FCM no. 98) with SML (T) = 15 mg/kg and acetaldehyde (FCM no. 128) with SML (T) = 6 mg/kg. Taking into account the above made assumptions of the worst calculations we can confirm that the SML values for both substances are not exceeded under these conditions. In addition, also a small amount of methanol (CAS no. 67-56-1) is formed. This substance is listed in the Plastics Regulation under FCM no. 117 without a restriction. We assume that this NIAS evaporates during the drying process.

A further by-product of the polymerisation is methyl acetate (CAS no. 79-20-9). This substance is not listed in the Plastics Regulation but is permitted as a flavouring substance in Europe under the FL no. 09.023 (see remark below the SML table regarding food additives and flavourings).
A further by-product is ethyl acetate (CAS no. 141-78-6). This substance is listed in the Plastics Regulation under FCM no. 327 without a restriction. We assume that the small amount of this NIAS evaporates during the drying process.

- ***Decomposition products***

For the polymersation of vinyl acetate, peroxides such as tert. butyl hydroperoxide (CAS no. 75-91-2) and hydrogen peroxide (CAS no. 7722-84-1) are absolutely necessary as initiators. These substances decompose during the reaction and create tert. butanol and water as NIAS. Due to the fact that initiators are used at a very low level the quantity of both decomposition products is very low and we assume that both evaporate during the drying process.

AQUENCE BG 9040 LM is a water-based product. Water-based products typically need a preservative or biocide system to protect the polymer against mold and bacteria during shelf life. These preservatives decompose during shelf life. The biocide degradation is influenced by numerous chemical and physical parameters, i.e. a biocide can decompose differently depending on the formulation, triggered by various chemicals, pH, temperature etc. It is therefore difficult to define NIAS for all preservatives.

The biocide 1,6-dihydroxy-2,5-dioxahexane (CAS no. 3586-55-8) is known to decompose into ethylene glycol (CAS no. 107-21-1) and formaldehyde (CAS no. 50-00-0). Both substances are

evaluated on European level because they are listed in the Union List with an SML value of SML (T) = 30 mg/kg for FCM no. 227 (ethylene glycol) and SML (T) = 15 mg/kg for FCM no. 98 (formaldehyde). Estimating that the whole quantity of ethylene glycol and formaldehyde were released in one step, which is never the case as there is always an equilibrium in the wet adhesive system, the maximum allowed specific migration value would not be exceeded under the worst case conditions assumed above.

The product contains urea as part of the formulation. It is well-known that during the manufacturing of urea the formation of a small amount of imidodicarbonic acid (Biuret, CAS no. 108-19-0) is technically unavoidable. Imidodicarbonic acid is not listed in the Union List of the Plastics Regulation.

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 21st November 2014. 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 8th September 2014.

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. The information may contain trade secrets and must be treated strictly confidential; it must not be disclosed or made accessible to third parties.

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

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