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To whom it may concern,

Issue Date: 22.08.2018

Expiration Date: 19.08.2019

Your message

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Declaration with Food Contact Regulation

Dear Sir or Madam,

Referring to your request concerning the food contact regulation compliance status, we can declare the following for our product **AQUENCE CW 21058**:

EU Food contact regulations:

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

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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) 2017/752 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 CW 21058 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 those migratable monomers and starting substances of the adhesive, which are restricted with specific limits.

In this table only substances are listed, which are subject to restrictions. All substances listed in the Plastics Regulation without an 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 (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.

FCM no.	CAS no.	Name	SML / Limitation	Specific migration test necessary
231	000108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg	No
115 ¹⁾	000064-19-7	Acetic acid (as sodium salt, E 262)		see remark1)
511 ¹⁾	007664-93-9	Sulphuric acid (as sodium salt, E 514)		see remark1)



----- ^{2), 3)}	000052-51-7	2-Bromo-2-nitropropane-1,3-diole	max 0.032 mg/dm ² in dispersion film	
----- ^{2), 3)}	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	max 0.003 mg/dm ² in dispersion film	No
451 ²⁾	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0.5 mg/kg	No

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

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) 2017/752 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 are named in the table above or in chapter 'NIAS'.



Epoxy Regulation

AQUENCE CW 21058 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)

All raw materials in the formulation of our adhesive AQUENCE CW 21058 are listed in either the XIV. or XXXVI. BfR recommendation for the direct food contact.

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.

- **Decomposition products**

For the polymerisation 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 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.

China Food Contact Regulations:

GB 4806.1-2016 General safety requirements for food contact materials and articles

Paragraph 3 of the Regulation GB 4806.1-2016 requires that materials and articles, coming into contact with food or reasonably be expected to come 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 cannot test the special conditions of each customer. The organoleptic characteristics can be monitored only on the packaged foodstuff and therefore fall under the responsibility of the product user.

GB 31603-2015 good manufacturing practice for food contact materials and articles

Clause 3.7 of the Regulation GB 4806.1-2016 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. We can confirm that the product manufacturing practice in Henkel Humen Plant can meet the adhesive relevant items in GB31603-2015.

Our process documentation of each manufacturing stage enables us to provide the appropriate authorities with the necessary information at any time.

GB 9685-2016 Standard for the use of additives in food contact materials and articles

The standard GB 9685-2016 and other product standards can so far be used to assess the safety of materials and articles in contact with foodstuffs in China, including adhesives. The basic standard GB 9685-2016 contains positive lists with 'monomers and additives' only, that can be used in food contact materials and their articles.

In accordance with Appendix A of the Regulation GB 9685-2016 on materials and their articles intended to come into contact with food, the overall migration limit (OML) for all substances without any restrictions shall not exceed 60 mg/kg food. For many substances specific migration limits (SML) or other restrictions are specified in the Regulation GB 9685-2016 and must be respected.



All components of the product named above are listed in A.5 of GB 9685-2016 and therefore it complies with the standard as food contact adhesive application.

The below table lists those substances which are subject to restrictions. All substances, which are listed in GB 9685-2016 but without any SML value, are covered by the compliance with the overall migration and do not require any additional monitoring.

AQUENCE GD900F (638204)

FCA no.	CAS no.	Name	Maximum level /%	SML/QM/(mg/kg)	Remark
--1)	Acetic acid ethenyl ester, polymer with ethene, and ethenol	26221-27-2	Used appropriately according to the production demand	12 (vinyl acetate: SML)	It is not allowed to be used to contact food with >8% ethanol
FCA0952	Polyvinyl acetate	9003-20-7	Used appropriately according to the production demand	12 (vinyl acetate: SML)	Adhesives in food contact materials and their products
FCA0277	Methyl-3 (2H) - isothiazolone	2682-20-4	Used appropriately according to the production demand	0.5 (SML)	Adhesives in food contact materials and their products

1) It is not listed in A.5 of GB 9685-2016, but it is listed in "107 resins authorized for food contact use "(MOH Notice No. 23, 2011), and GB4806.6-2016 as basic resin for direct food contact plastic. Since resin list for food contact adhesive are not yet published, above mentioned two positive list can be reference for adhesive compliance and safety assessment.

GB 4806.1-2016 Regulates food contact materials and articles in their finished state. Therefore, the above mentioned restricted lists can only be guidance for the examination of the finished product. As the 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 Clause 3.6 of GB 31604.1-2016 General principles for migration experiment, migration testing should be carried out on the finished article under actual conditions of use. For the realization of the migration tests please consider GB 31604.1-2015 and GB5009.156 General rules of the pre-treatment method of the migration test for food contact materials and articles.

NIAS

Please refer to above EU statement chapter. The limited test on adhesive itself shows that the mentioned NIAS Formaldehyde (CAS 50-00-0) and Methanol (CAS 67-56-1) are both on ppm level, based on EU cube approach (as mentioned above) worst case calculation, the migration of mentioned impurities should be less than 10 ppb.



US Food Contact regulation:

21 CFR

AQUENCE CW 21058 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 CW 21058 is in compositional compliance with the Indirect Food Additives regulation 21 CFR 176.170 'Paper and paper board for contact with Aqueous and Fatty food'.

AQUENCE CW 21058 is in compositional compliance with the Indirect Food Additives regulation 21 CFR 175.105 'Adhesives'.

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.

Kind regards

Nini Lin 林英妮

Product Safety and Regulatory Affairs Manager

Disclaimer:

The information being provided regarding the substances contained in these products comes from reviewing information provided by the suppliers or producers of the raw material used in these products. Henkel may not have conducted any tests to determine the actual presence of these substances in the above products. No warranties are given; all implied warranties of merchantability or fitness for a particular purpose and all other express or implied representations are expressly excluded.