

Declaration of Compliance

According to Regulation (EC) 1935/2004, Article 16

1. Identity of business:

Colourtone Masterbatch Ltd Pantglas Farm Industrial Estate Newport Road Bedwas Caerphilly CF83 8YE

- 2. Identity of materials: Masterbatches for use in plastics. Specifically those shown in spreadsheet 'Kwik-Lok Masterbatches v2' dated February 2016
- 3. Declaration date: February 2nd 2016
- 4. General Declaration

Colourtone Masterbatch Ltd confirms that the masterbatches described above and supplied to Kwik-Lok comply with the requirements of Article 3 of Regulation (EC) No.1935/2004 and are produced under conditions of good manufacturing practice in accordance with Regulation (EC) No.2023/2006.

Colourtone operates a quality control and assurance system as required by Articles 5, 6 and 7 of Regulation (EC) No.2023/2006. This quality system has been assessed and registered by NQA against the requirements of BS EN ISO 9001:2008 (certificate No.10301).

Specific measures for plastics according to Regulation (EC) No. 1935/2004 Article 5 (Annex 1, Item 10) are covered by Regulation (EU) No.10/2011 (consolidation of EU Directive 2002/72/EC as amended) and include lists of authorised substances and requirements for overall and specific migration.

Only monomers and starting substances listed in Table 1 of Annex I of Regulation (EU) No.10/2011 (as amended) are used in the polymer carriers of the masterbatches described above.

Additives used in the manufacture of these masterbatches are present in Table 1 of Annex I of Regulation (EU) No.10/2011 (as amended).

Regulation (EU) No.10/2011 (as amended) includes a specification for carbon black pigment to be used in food-contact applications.

The grades of carbon black used in the masterbatches described above are in compliance with this specification. Limitations on the addition rates of masterbatches associated with the specification for carbon black are shown in the spreadsheet described in para.2.

Overall Migration

Colourtone Masterbatch Ltd believes that the above masterbatches, when used under conditions of good manufacturing practice, at an appropriate addition level, are capable of satisfying the overall migration test limits of Article 12 of Regulation (EU) No.10/2011 (as amended).

It should be recognised that compliance with the overall migration requirements stipulated in Article 12 can only be demonstrated by tests carried out on the material or article in the finished state in which it will contact the foodstuff. Colourtone Masterbatch Ltd is therefore unable to make any indications regarding the likely requirements for testing and re-testing of Kwik-Lok's products. It is recommended that an appropriate testing frequency is established from actual test results obtained by Kwik-Lok and consultation of appropriate publications on the subject.

5. Heavy Metal Compliance

We certify that the products described above are free from raw materials based on heavy metals (i.e. lead, cadmium, mercury and hexavalent chromium) and are suitable for use in packaging applications under Directive 94/62/EC (as amended). All colorants are in compliance with the purity standards described in European Resolution AP(89)1.

Colourtone does not conduct testing to determine the levels of any heavy metals that may be present as trace impurities.

6. Specific Migration Limits

Substances that are subject to specific migration limits (SML) according to Regulation (EU) No.10/2011 Annex I Table 1 (as amended) and contained in these masterbatches are shown in the spreadsheet detailed in para.2. See also section 7.

7. Restrictions on Materials and Articles

Annex II para.1 of Regulation (EU) No.10/2011 (as amended) lists SML for certain metallic elements. Whilst we do not expect that there will be any measurable migration of these elements resulting from the inclusion of raw materials containing them in the masterbatches supplied to Kwik-Lok, for information purposes the percentage of these elements present is shown for each masterbatch in the spreadsheet described above. This composition information may be subject to minor variation as a result of colour control measures during manufacture of the masterbatches.

8. Restrictions on Hazardous Substances (RoHS)

Colourtone confirms that there are no raw materials restricted from use in electrical and electronic equipment as stated in EU Directive 2011/65/EC (as amended) present in the formulation of the masterbatches described in para.2.

9. Dual Use Additives

Components of these masterbatches that are also listed in European Directives as food additives are shown in the spreadsheet described in para.2.

10. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No. 1907/2006 (as amended).

Colourtone confirms that, based on information provided by our raw material suppliers, it is our understanding that all substances used by Colourtone Masterbatch in the manufacture of the masterbatches described above have been pre-registered in the initial phase of the introduction of the REACH Regulation.

The products manufactured by Colourtone are classified in REACH as mixtures and are not, therefore, required to themselves be registered under the REACH legislation.

We are unable to supply pre-registration numbers for the raw materials in our products as this information is not provided by our suppliers and this is not a statutory requirement.

The European Chemicals Agency (ECHA) periodically introduces amendments to the candidate list of substances of very high concern (SHVC) for potential inclusion in Annex XIV (substances requiring Authorisation for continued use). There are no SVHC present in any of the masterbatches shown in the spreadsheet described in para.2.

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Paul Denton Technical Manager

Technical information supplied corresponds to the best of our knowledge at the time of writing. No warranty is expressed or implied regarding the accuracy of the information, the results to be obtained from the use of the product or that use will not infringe any patent. Any user of the product is responsible for determining its suitability for the intended process and application and compliance with any relevant regulations.