

## FOOD CONTACT COMPLIANCE DECLARATION

The antimicrobial masterbatch products listed below are supplied by Addmaster Ltd, holders of the following certified Management Systems

- ISO 9001:2008
- ISO 14001:2004

Business operator

Addmaster (UK) Ltd, Darfin House, Priestly Court, Staffordshire Technology Park, Stafford,  
ST18 0AR

Product type covered by this Declaration

Antimicrobial Masterbatch

Product names covered

- Biomaster 612

Compliance with Regulations

The products referred to above are listed in reference to the following regulations/Directives:

Directive 2002/72/EC – Commission Regulation (EU) No 10/2011

The active ingredient is present on the Provisional list of additives used in plastics relating to Directive 2002/72/EC. As from 1 January 2010 the list of additives in Directive 2002/72/EC relating to materials and article intended to come into contact with foodstuffs became a positive list to the exclusion of all others. Commission Regulation (EU) No 10/2011 consolidates the rules in the Plastic Directives 2002/72/EC. Substances on the provisional list may continue to be used in accordance with National legislation until a decision on their inclusion or non-inclusion into the positive list is taken.

## EFSA Opinion

Appears on the 12th list of substances for food contact materials

## UK Status

It is the responsibility of individual member states to legislate the silver additives until a decision is made within the EU regarding inclusion into the positive list. The UK does not have any specific restriction or rules on the silver additives they are therefore permitted on the UK market until their status is resolved.

## BPR

Supported under product type 2, 4, 7 and 9 of the Regulation (EU) No 528/2012

## Restrictions of use for Food Contact

- 0.05 mg Ag/Kg food, based on the human NOEL of about 10g of silver for a total lifetime oral intake allocated by WHO (WHO, 2004) for drinking water
- National guidelines – reference needs to be made in regards National allowance for use of this product in Direct Food Contact.

## Specific Migratory Limits

- None of the monomers present in the polymeric carrier is subject to a Specific Migratory Limit

## Presence of dual use additives

- None of the additives present in this polymer is subject to a restriction in food as referred to in Article 11.3 of EU Regulation 10/2011

## Conditions of Use

- Suitable for use in SAN or ABS
- Suited to let down rates between 2% - 3.0%
- Within working temperature range of SAN or ABS

## Additional Comments

The treated article will be required to comply with labelling requirements of the BPR as of 1<sup>st</sup> September 2013 these apply to the "placing on the market", but not the subsequent supply

## Traceability

Addmaster (UK) Ltd has in place the necessary system, records and procedures to ensure traceability of materials and products in order to facilitate any necessary control and recall of product

## Confirmation of Declaration of Compliance

This Declaration was prepared on behalf of Addmaster (UK) Ltd and the information included is to the best of our knowledge correct.

Any questions should be forwarded using the details below

Signed for and on behalf of Addmaster (UK) Ltd



Lesley Taylor

Regulatory Affairs Manager

[Lesley.taylor@addmaster.co.uk](mailto:Lesley.taylor@addmaster.co.uk)

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- ISO 9001:2008
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Business operator

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ST18 0AR

Product type covered by this Declaration

Antimicrobial Masterbatch

Product names covered

- Biomaster 966

Compliance with Regulations

The products referred to above are listed in reference to the following regulations/Directives:

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

Directive 2002/72/EC – Commission Regulation (EU) No 10/2011

The active ingredient is present on the Provisional list of additives used in plastics relating to Directive 2002/72/EC. As from 1 January 2010 the list of additives in Directive 2002/72/EC relating to materials and article intended to come into contact with foodstuffs became a positive list to the exclusion of all others. Commission Regulation (EU) No 10/2011 consolidates the rules in the Plastic Directives 2002/72/EC. Substances on the provisional list may continue to be used in accordance with National legislation until a decision on their inclusion or non-inclusion into the positive list is taken.

## EFSA Opinion

Appears on the 12th list of substances for food contact materials

## UK Status

It is the responsibility of individual member states to legislate the silver additives until a decision is made within the EU regarding inclusion into the positive list. The UK does not have any specific restriction or rules on the silver additives they are therefore permitted on the UK market until their status is resolved.

## BPR

Supported under product type 1, 2, 4, 6, 7, 9, 10 and 11 of the Regulation (EU) No 528/2012

## Restrictions of use for Food Contact

- 0.05 mg Ag/Kg food, based on the human NOEL of about 10g of silver for a total lifetime oral intake allocated by WHO (WHO, 2004) for drinking water
- National guidelines – reference needs to be made in regards National allowance for use of this product in Direct Food Contact.

## Specific Migratory Limits

- None of the monomers present in the polymeric carrier is subject to a Specific Migratory Limit

## Presence of dual use additives

None of the additives present in this polymer is subject to a restriction in food as referred to in Article 11.3 of EU Regulation 10/2011

## Conditions of Use

- Suitable for use in PE
- Suited to let down rate of 1%
- Within working temperature range of PE

## Additional Comments

The treated article will be required to comply with labelling requirements of the BPR as of 1<sup>st</sup> September 2013 these apply to the “placing on the market”, but not the subsequent supply

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### Business operator

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ST18 0AR

### Product type covered by this Declaration

Antimicrobial Masterbatch

### Product names covered

- Biomaster 1561

### Compliance with Regulations

The products referred to above are listed in reference to the following regulations/Directives:

Directive 2002/72/EC – Commission Regulation (EU) No 10/2011

The active ingredient is present on the Provisional list of additives used in plastics relating to Directive 2002/72/EC. As from 1 January 2010 the list of additives in Directive 2002/72/EC relating to materials and article intended to come into contact with foodstuffs became a positive list to the exclusion of all others. Commission Regulation (EU) No 10/2011 consolidates the rules in the Plastic Directives 2002/72/EC. Substances on the provisional list may continue to be used in accordance with National legislation until a decision on their inclusion or non-inclusion into the positive list is taken.

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## BPR

Supported under product type 2, 4, 7 and 9 of the Regulation (EU) No 528/2012

## Restrictions of use for Food Contact

- 0.05 mg Ag/Kg food, based on the human NOEL of about 10g of silver for a total lifetime oral intake allocated by WHO (WHO, 2004) for drinking water
- National guidelines – reference needs to be made in regards National allowance for use of this product in Direct Food Contact.

## Specific Migratory Limits

- None of the monomers present in the polymeric carrier is subject to a Specific Migratory Limit

## Presence of dual use additives

FCM name	E number	Food additive name
Carbonic acid salts	E170	Calcium carbonate
Iron oxide	E172	Iron oxides
Silicon dioxide	E551	

## Conditions of Use

- Suitable for use in polymers
- Suited to let down rate of 1% - 2%
- Within working temperature range of polymers



## Additional Comments

The treated article will be required to comply with labelling requirements of the BPR as of 1<sup>st</sup> September 2013 these apply to the "placing on the market", but not the subsequent supply

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# ISO 22196:2011 Antimicrobial Test Certificate

This is to certify that

**Shower Handle with Biomaster**

supplied by

**EAM Benelux**

have been tested to ISO 22196:2011 and shown to reduce the organisms below compared to untreated samples:-

*Staph aureus* by  $\geq 98.83\%$

*Escherichia coli* by  $\geq 99.94\%$

Date of test(s):	April 2019
Test laboratory:	Industrial Microbiological Services Limited Registered in England 3264423
Certificate No(s).	1037496.49/12989



Paul Phillips  
Technical Manager



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This is to certify that

**Shower Head with Biomaster**

supplied by

**EAM Benelux**

have been tested to ISO 22196:2011 and shown to reduce the organisms below compared to untreated samples:-

*Staph aureus* by  $\geq 99.84\%$

*Escherichia coli* by  $\geq 99.94\%$

Date of test(s):	April 2019
Test laboratory:	Industrial Microbiological Services Limited Registered in England 3264423
Certificate No(s).	1037496.37/12990 & 1037496.31/12991



Paul Phillips  
Technical Manager

