January 2020

Biocidal Products Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012

Article 95 – "Transitional Measures concerning access to the active substance dossier"

The objective of Article 95 is to ensure the objectives set out in recital 8

"To ensure the equal treatment of persons placing active substances on the market, they should be required to hold a dossier or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products"

This is aimed mainly at alternative suppliers, who do not support the union approval of an active but benefit from the regulatory regime. This is implemented through the publication by ECHA of the list of active substances suppliers who have made a submission under Article 95.

Only biocidal products containing an active substance supplied from an entity on the list may now be made available on the market as we have passed the 1st September 2015.

Addmaster can confirm that all of the actives used in Biomaster products are supplied by entities on the ECHA list of active substance suppliers. For this reason Addmaster customers can continue to place product onto the market in compliance with Article 95

Any additional questions can 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

Regulatory Status

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

- ISO 9001:2015
- ISO 14001:2015

Business operator

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

ST18 0AR

Product type covered by this Declaration

Antimicrobial Additives

Product names covered

- Biomaster range of additives – powders, polymers and liquids

Compliance with Regulations

EU Regulation

- The active ingredients incorporated into the Biomaster range of products are currently going through the review process of the Biocidal Product Regulation - BPR regulation 528/2012. The dossiers for these were originally submitted in line with the requirements of the Biocidal Products Directive – BPD 2002/72/EC. This means that products can remain on the market until the review is completed.

- Current requirements for sale of our additives under the Biomaster brand are that the active is purchased from a supplier on the ECHA list of approved suppliers in line with Article 95 of the BPR. All Biomaster actives comply with this and a separate statement can be supplied upon request. There is also a requirement that any treated articles are labelling in line with the requirements of Article 58. A label example can be provided upon request.

- It is important to highlight that any claims relating to the treated article need to be considered carefully to maintain the items status as a treated article. Biocidal product claims about the article could result in additional registration requirements later.

- Once the review of the active is completed and it has been through the appropriate committee's silver will be listed for inclusion into the appropriate Annex. At this point there will be a requirement to complete registration of the biocidal products. This will involve the completion of product dossiers to include efficacy data, environmental data and risk analysis of end use.

- Although it is important to highlight that the exact date for delivery of these dossiers is still uncertain, we are in the process of developing product families under the Biomaster brand. This will allow our customers to sell registered biocidal products for incorporation into treated articles.

- This means that it is important that Addmaster is aware of end use applications to allow for its inclusion within the scope of the family and that all claims are substantiated and within scope of those allowed for treated articles.

USA

- Addmaster have a range of registered additives for use in the USA under the treated article exemption. This relates to PRN 2000 – 1, which allows treated articles to be sold in line with the EPA labels

- Sale of product in the USA is under certain allowed Marketing claims, for this reason Addmaster needs to see all claims relating to the technology for product being sold in the USA

Additional Comments

This document is designed to give a brief outline of the current regulatory landscape as Addmaster (UK) Ltd. sees it. It is important to highlight the area of biocides is developing rapidly and things are constantly changing it is the customers responsibility to ensure they have the latest understanding of the regulatory requirements.

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