



Micro contaminants in CMC

2015

Contents

Introduction	3
Microbiology	3
Heavy metals	3
Pesticides	4
Mycotoxines	4

Introduction

CMC is produced in the Akzo Nobel Functional Chemicals plant in Arnhem, The Netherlands. This production facility comprises of two direct production lines and one mixing / milling line.

The production plant produces a range of CMC products which are used in a number of applications. Products for the food, healthcare and pharmaceutical industry are produced and controlled under strict specifications and all comply with all regulations.

CMC is produced from raw materials: cellulose, sodium hydroxide and monochloroacetic acid to produce a water soluble cellulose derivate.

Over time our company has received a range of requests and requirements for the analysis and reporting of micro contaminants. This report covers the results of the most important requests and requirements over the year 2015.

Microbiology

Microbiology is a standard test for the release of CMC product. The bioburden level is a plant and operation characteristic, it is not influenced by the product type produced. The CMC production process has a number of consecutive killing steps, which makes the overall production process bioburden low.

Microbiology	Limit cfu / g	Number of Measurements n	Number of out of spec n	Average cfu
Total plate count	1000	435	2	<1*
Yeasts	100	436	4	<1*
Moulds	100	436	1	<1*
E-coli	n.d. / 10 g	427	0	<1
Salmonella	n.d. / 10 g	426	0	<1
Staph. Aureus	n.d. / 10 g	450	0	<1
Pseu. Aeruginosa	n.d. / 10 g	424	0	<1
Enterobacteriaceae		2	0	<1
Fecale enterococcon	max 10/g	2	0	<1
Sulfite reducing clostridia	max 10/g	2	0	<1
Clostridia perfringens	max 10/g	2	0	<1

Microbiology testing is performed on intermittent basis.

*Offspec situations taken out and segregated)

Heavy metals

Heavy metal content of CMC is mainly derived from its raw material sources. Please note that the sodium hydroxide process does not use mercury (any longer).

Please find below an overview of the heavy metal results:

Heavy metals	Number of Measurements n	Average ug / kg	Maximum value ug / kg
Antimony (Sb)	8	<10	<10

Arsenic (As)	8	<15	<15
Bismuth (Bi)	8	<2	<2
Cadmium (Cd)	8	<1	1.4
Copper (Cu)	4	89	130
Lead (Pb)	8	65	280
Mercury (Hg)	8	<2.5	<2.5
Tin (Sn)	8	<50	110

Heavy metal analysis are performed on intermittent basis.

Pesticides

The only possible source of pesticide in CMC is the raw material cellulose which is derived from either cotton seed linters or wood. CMC's derived from both sources have been extensively tested in a comprehensive investigation. No chlorine, phosphorous or nitrogen based pesticides have been detected in ether sourced CMC.

Mycotoxines

Mycotoxines are mould produced components. They are created either during growth of produce or during storage. In all cases the temperature, humidity, time of storage are important. Because CMC is produced from the raw material cellulose its mycotoxines concentration needs to be evaluated.

Important in the mycotoxines evaluation is its suggested stability, which has basis in fact under normal "food-processing" circumstances. However, the CMC production involves a number of extreme conditions which have an important impact on any possible mycotoxines present.

The following mycotines groups have been studied and their potential to survive the chemical conditions in the plant:

1. Aflotoxines
2. Ochratoxines
3. Deoxynivalenol
4. Fumonisine
5. Patuline
6. Zearalenone
7. Citrine
8. Cyclopiazonic acid
9. Moniliformine
10. Sterigmatocystine

None of the above are a potential risk to the CMC production quality. Please refer to the risk analysis¹ for further information.

¹ Report: Beschouwing en risico analyse op het voorkomen van mycotoxines in gezuiverde CMC, CJ 't Hart, 3/7/2006