GLOBAL STANDARD

gemeinnützige GmbH



The Global Organic Textile Standard (GOTS) specifically prohibits the use of any chemical input that releases carcinogenic aryl amine compounds MAK III categories 1,2,3,4. (**Section 2.3.1**, excerpt below).

Inputs (e.g. azo dyes and pigments) releasing carcinogenic	Prohibited
arylamine compounds (MAK III, category 1,2,3,4)	

This includes aniline which is classified as MAK III Category 4 chemical.

GOTS recognises that even when material is produced to GOTS standards, there could be the possibility of unintended or unknown sources of contamination, which is why residue limits for certain chemicals have been specified for GOTS Goods under **Section 2.4.15**, see excerpt below:

Arylamines with carcinogenic properties (amine-releasing azo dyes MAK III, category 1,2,3)	< 20 mg/kg	Test method : EN 14362- 1 and -3 (HPLC/GCMS)
Aniline (MAK III, category 4)	< 100 mg/kg	,

Worldwide, most institutions have similar views on aniline.

- MAK: The Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) under the statutes of DFG (Deutsche Forschungsgemeinschaft e.V.) proposes maximum workplace and biological values for chemicals, based on which substances are categorised as carcinogenic, mutagenic, sensitizing etc. Aniline has been classified as MAK III category 4, or a substance with carcinogenic potential for which a non-genotoxic mode of action is of prime importance; no significant contribution to human cancer risk is expected at exposures at MAK and BAT values. (ref.)
- The <u>IARC</u> which is a part of the World Health Organisation (WHO) classifies Aniline under Group 3, that is "*Not classifiable as to its carcinogenicity to humans*".
- EU Regulation EC/1272/2008 classifies Aniline as a category 2 (suspected) carcinogen.
- <u>USEPA suggests that Aniline</u> could be a suspected carcinogen and there is no evidence of being carcinogenic by itself.

Aniline is known to possess slight contact sensitising potential.

There is no legal or scientific reference or study related safe limit values for aniline. However, it is logical that residual unintended limit values for aniline should be higher than those for chemicals classified under MAK III Categories 1,2 and 3. Based on these facts and discussions with experts, the GOTS Standards Committee decided to define a realistic and appropriate residue limit keeping in mind aniline's hazard potential and practicability.

Given these circumstances, GOTS feels that their residual, unintended use limit of 100 mg/kg, with current understanding and knowledge is adequate to ensure safety of consumers and in line with its larger philosophy of sustainability.

Global Standard gemeinnützige GmbH is the non profit operating unit of the GOTS International Working Group, charged with executing the Global Organic Textile Standard Program.