EUROPEAN CO-ORDINATION OF NOTIFIED BODIES NB-TOYS	**Co-ordination of the Notified Bodies NB-TOYS under the Safety of Toys Directive**	**NB-TOYS/2012/26** 23 April 2012

EC type approval protocol No. 2 Microbiological safety of toys containing aqueous media

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Microbiological safety of toys containing aqueous media

Introduction

This protocol intends to specify microbiological requirements for toys specified in the scope. Micro-organisms are known to proliferate in the presence of water, therefore the primary hazard is related to aqueous media.

If pathogenic micro-organisms are present in toys they may present a risk of microbial infection. As no specific microbiological requirements for toys exist the Notified Body toys group has developed a harmonised protocol based on requirements that are applicable for cosmetic products.
Relevant exposure routes for microbiological evaluation are:
- skin contact;
- eye, ears or nose contact (mucous membranes);
- ingestion.

If an infection respectively intoxication occurs in the body after an intake of microorganisms depends on different factors:
- minimum infection dose of the germ;
- ability of the immune system to ward off germs;
- pH-value and aW-value of the product;
- matrix into which the germs are embedded: fat and protein form a protection colloid around the germs, so that the stomach-intestine-passage remains mostly unscathed;
- amount of the product which possibly comes into the body of a child.

1. Scope

1.1 Aqueous liquid
Aqueous liquid: a water containing liquid/paste in a toy or on a toy or accompanying a toy which the child is likely to become exposed during normal or foreseeable use of the toy (e.g. liquid paints, bubble liquids, ink in pens, liquid provided with toys for squirting, liquid in teethers and pacifiers).

1.2 Modelling clays based on aqueous formulations
Remark: Some clays are not based on water or do not contain any significant quantity of water. This means they have very low water activity and so are not prone to microbiological attack or breakdown. Oven hardened modelling compounds might be an example as well as plastercine. Therefore the scope is restricted to modelling clays based on aqueous formulations.

1.3 Finger paints

1.4 Gell's and semi-liquids based on aqueous formulations
Remark: Some non-aqueous gels are used inside some toys,eg in place of sand in a timer or a fully encapsulated "slime". These are exempted as there would be not microbiological hazard if they leaked. Examples would be high viscosity hydrocarbons

2. Limits

The sample has to comply with:

Total aerobic microbial count [1]	≤ 1000 cfu/g or ml
yeast and mould	≤ 10 cfu/g or ml
Staphylococcus aureus	Absent in 1 ml or g
Pseudomonas aeruginosa	Absent in 1 ml or g
Candida albicans	Absent in 1 ml or g
Escherichia Coli or Enterococci faecalis in liquids	Absent in 1 ml or g
Salmonella spp.	Absent in 1 ml or g
Enterobacteriaceae	≤ 10 cfu/g or ml

NOTE: [1] Great care is required in using this measure because it is not a good indicator of the risk posed. For example many categories for food such as fresh fruit and vegetables, cooked meats, sandwiches especially with salad fillings, cream cakes, pastries, cheesecake etc all are considered acceptable to eat if they have a TAMC of 10^5 to 10^7 (10 E5 to 10 E7) c.f.u per gram.

3. Test procedures

Following methods can be used:

3.1 Test for microbial contamination European Pharmacopeia EP

a) European Pharmacopeia, ("microbiological examination of non-sterile products") Chapter 2.6.12 (2)
b) European Pharmacopeia, ("microbiological examination of non-sterile products") Chapter 2.6.13 (2)
c) European Pharmacopeia, ("efficacy of antimicrobial preservation") Chapter 5.1.3 (2)

3.2 United States Pharmacopeia USP

a) USP "Microbiological examination of non-sterile products: Microbial enumeration tests", USP 31, chapter 61, latest edition
b) USP "Microbiolgical examination of non-sterile products: Tests for specific microorganisms", USP 31, chapter 62, latest edition

3.3 The European methods for the microbiological testing of cosmetics

a) EN ISO 18416 Detection of *Candida albicans* (ISO 18416)
b) EN ISO 21148 General instruction for microbiological examination (ISO 21148)
c) EN ISO 21149 Enumeration and detection of aerobic mesophilic bacteria (ISO 21149)
d) EN ISO 21150 Detection of *Escherichia coli* (ISO 21150)
e) EN ISO 22716 Guidelines on Good Manufacturing Practices (ISO 22716)
f) EN ISO 22717 Detection of *pseudomonas aeruginosa* (ISO 22717)
g) EN ISO 22718 Detection of *Staphylococcus aureus* (ISO 22718)

3.4 The European methods for the microbiological testing of water and foods

4. General remarks

4.1 If the specification is applied to raw materials than failures could occur which do not actually represent a real risk in the final toy because in the final toy other ingredients may act as biocides or preservatives. So it is inappropriate to expect that the technical dossier should contain microbiological test data for raw materials.

NOTE [2] Latest edition should be consulted

4.2 The limits mentioned in the table are the limits using the European test methods. In case the test method from the United States is used, the test results have to be converted to the European test methods.

4.3 This specification/protocol is inappropriate to apply to products that are consumer complaint returns because there is no way to establish what adverse treatments have been given to the toy before being returned as a complaint.

4.4 Care is needed with restrictions on E.Coli: E.coli should be limited to pathogens. Most coliform bacteria are not indicative of fecal contamination and are not harmful.

4.5 Please note that for cosmetic testing no methods for Salmonella and Enterobacteriaceae have been developed.