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# Analytical Services

## Nitrosamine Analysis

N-Nitrosamines are formed from secondary amines which are generated by the decomposition of certain rubber accelerators and which react with nitrous oxides during mixing and curing. They are known 'animal carcinogens' and there are a number of regulations in existence on the following products or areas:

### Bottle teats:

- FDA - solvent extraction

The FDA allows a total of 60ppb but will take action when any individual nitrosamine is present at a level of 10ppb or more. No further regulations regarding bottle teats or any other product are known to exist in the USA or Canada.

- CEN (EN12868) - artificial saliva extraction

The European Directive 93/11/EEC states that migration into the test medium must not exceed 0.1mg/kg for nitrosamines and 0.1mg/kg for nitrosatable amines.

### Balloons:

- Balloons now come under the Toy Safety Standard EN71 part 12: EU-EN 71-12:2013 – N-Nitrosamines and N-Nitrosatable Substances in Toys. Limits are 0.05mg/kg for sum of nitrosamines and 1mg/kg for nitrosatable amines.

### Condoms:

- There is an ISO Standard for condoms – ISO29941:2010. Condoms – Determination of nitrosamines migrating from natural rubber latex condoms. (Some providers prefer to measure nitrosatable amines also *via* EN12868)

### Food contact:

- There are a number of European Directives/Regulations. Please contact us to discuss these. Nitrosamines are one of the target species and migration tests are required. Migration time, migration media and temperature are established according to product type and likely contact.

### Airborne:

- TRGS 552  
These limits for working atmospheres are in place in Germany only, but are sometimes used as guidelines by other countries wishing to address the issue in production and storage areas. The TRGS 552 guidelines state a maximum of 1µg/m<sup>3</sup>.

**Rubber Consultants offers a testing service for all the categories above using UKAS accredited methods.**

For further information please contact one of our team  
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