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STATUTORY INSTRUMENTS

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**1995 No. 1012**

**CONSUMER PROTECTION**

**The N-nitrosamines and N-nitrosatable Substances in Elastomer or Rubber Teats and Dummies (Safety) Regulations 1995**

<i>Made</i>	- - - -	<i>4th April 1995</i>
<i>Laid before Parliament</i>		<i>6th April 1995</i>
<i>Coming into force</i>	- -	<i>28th April 1995</i>

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987(1), consulted such organisations as appear to him to be representative of interests substantially affected by these Regulations, the Health and Safety Commission and such other persons as he considers appropriate;

Now, therefore, the Secretary of State, in exercise of the powers conferred upon him by section 11 of the said Act, makes the following Regulations: –

**Citation and Commencement**

1. These Regulations may be cited as the N-nitrosamines and N-nitrosatable Substances in Elastomer or Rubber Teats and Dummies (Safety) Regulations 1995 and shall come into force on 28th April 1995.

**Interpretation**

2. In these Regulations –

“N-nitrosatable substances” means any substances capable of being converted into N-nitrosamines;

“dummy” means a soother and includes an article made of elastomer or rubber used to satisfy sucking needs and to pacify infants;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply; and

“teat” includes a substitute nipple made of elastomer or rubber that when attached to a container holding a fluid permits a baby to obtain the fluid from the container by sucking.

### **Application**

3. These Regulations apply to teats and dummies which are intended to be, or are, brought into contact with foodstuffs.

### **Supply**

4. No person shall supply a teat or dummy unless the teat or dummy complies with the provisions of regulation 5 below.

### **Basic Rules and Criteria Applicable to the Method of Determining Release**

5. A teat or dummy shall not pass on to release-test liquid (saliva test solution) under the conditions specified in Schedule 1 to these Regulations any N-nitrosamine and N-nitrosatable substance detectable by a method which complies with the criteria laid down in Schedule 2 to these Regulations and which can detect the following quantities –

- (i) 0,01 mg in total of N-nitrosamines released/kg (of the parts of the teat or dummy made of elastomer or rubber); and
- (ii) 0,1 mg in total of N-nitrosatable substances/kg (of the parts of the teat or dummy made of elastomer or rubber).

4th April 1995

*Ferrers*  
Minister of State,  
Department of Trade and Industry

## SCHEDULE 1

regulation 5

### BASIC RULES FOR DETERMINING THE RELEASE OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES

#### Release-test liquid (saliva test solution)

1. To obtain the release-test liquid, dissolve 4,2g of sodium bicarbonate (NaHCO<sub>3</sub>), 0,5g of sodium chloride (NaCl), 0,2g of potassium carbonate (K<sub>2</sub>CO<sub>3</sub>) and 30,0 mg of sodium nitrite (NaNO<sub>2</sub>) in one litre of distilled water or water of equivalent quality. The solution must have a pH value of 9.

#### Test conditions

2. Samples of material obtained from an appropriate number of teats or dummies are immersed in the test release liquid for 24 hours at a temperature of 40±2 C.

## SCHEDULE 2

regulation 5

### CRITERIA APPLICABLE TO THE METHOD FOR DETERMINING THE RELEASE OF N-NITROSAMINES AND N-NITROSATABLE SUBSTANCES

1. The release of N-nitrosamines is determined in one aliquot of each solution obtained according to Schedule 1. The N-nitrosamines are extracted from the aliquot with nitrosamine-free dichloromethane (DCM) and determined by gas chromatography.

2. The release of N-nitrosatable substances is determined in another aliquot of each solution obtained according to Schedule 1. The nitrosatable substances are converted into nitrosamines by acidification of the aliquot with hydrochloric acid. Subsequently the nitrosamines are extracted from the solution with DCM and determined by gas chromatography.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations implement Commission Directive No. [93/11/EEC](#) concerning the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (OJ No. L93, 17.4.1993, p.37). This Directive is a specific Directive adopted pursuant to the provisions of Article 3 of Council Directive No. [89/109/EEC](#) on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (OJ No. L40, 11.2.1989, p.38) (the Council Directive). The Council Directive provides that such materials and articles must be manufactured in compliance with good manufacturing practices. This general duty is implemented by the provisions of regulation 4 of the Materials and Articles in Contact with Food Regulations 1987 (S.I. [1987/1528](#)) which applies to teats and soothers within the scope of these Regulations.

These Regulations apply to teats and soothers (referred to as “dummies” in these Regulations) intended to be (or which are) brought into contact with foodstuffs (regulation 3).

**Status:** *This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

The Regulations provide that the supply of a teat or dummy not complying with their requirements is prohibited (regulation 4).

Basic rules and criteria applicable to determining the release of substances are provided by these Regulations (regulation 5 and Schedule 1, and 2).

A Compliance Cost Assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies can also be obtained from the Consumer Affairs Division of the Department of Trade and Industry, Room 315, 10 – 18 Victoria Street, London SW1H 0NN.