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Foreword

This document EN 1400-2:2002 has been prepared by Technical Committee CEN/TC 252 "Child use and care articles", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This European Standard 1400 “Child use and care articles” consists of the following parts:

— *Part 1: General safety requirements and product information*

— *Part 2: Mechanical requirements and tests*

— *Part 3: Chemical requirements and tests*

This part of this European Standard contains one annex:

- annex A (informative) A suitable HPLC apparatus, method and precision data for determination of 2-Mercaptobenzothiazole (MBT) and/or antioxidants

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

Elastomeric and rubber teats are regulated by the Commission Directive 93/11/EEC concerning the release of *N*-Nitrosamine and *N*-Nitrosatable substances from elastomer or rubber teats and soothers. The current Directive provides in its annexes an outline method of analysis which, has been published as EN 12868.

A limit for the release of 2-mercaptobenzothiazole (MBT) has been specified in the standard. This limit significantly reduces the level of this substance potentially released from soothers. The Scientific Committee for Food has concluded that the limit does not constitute a health hazard. The limit for the release of MBT will be reconsidered in light of future studies and recommendations.

It is noted that all plastic components are regulated by the Commission Directive 90/128/EEC.

Commission Decision 198/815/EC with its subsequent extensions has adopted temporary measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age. The prohibition relates to such products made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP). At the time of preparing this standard a final decision was awaited. This standard will be reviewed in the light of that decision.

Formaldehyde, caprolactam and colourants have each been considered by the Technical Committee. They have not been included in the standard at this stage because of the lack of either adequate information for making a satisfactory potential risk assessment, or validated test methods for the determination of their migration levels from relevant products. They will be reconsidered when further information becomes available.

For similar reasons, latex protein allergy risk has also not been included in this standard. There is an extremely low incidence of latex protein allergy amongst babies and young children. Nevertheless, provision for packaging information for soothers containing natural rubber has been made in Part 1 of this standard. The issue of potential sensitisation and allergic reaction from rubber products will be re-considered when further information becomes available.

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