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Our reference

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Date

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**Advice by the Director of the Office for Risk
Assessment
To the Minister of Health, Welfare & Sport and the
Minister of Agriculture, Nature and Food Quality**

**Advice on the use of alternative plasticisers in toys and child
care articles**

Many plastics contain chemicals known as 'plasticisers', which serve to make the material soft and flexible. One of the main groups of chemicals traditionally used as plasticisers is the phthalates (substances derived from phthalic acid). However, European legislation now largely precludes the use of certain phthalates in soft plastics. The industry is therefore looking for alternatives. The Chief Product Safety Inspector has asked for an assessment of the risks associated with the use of three alternative plasticisers in toys and child care articles. The substances in question are diethylhexyl terephthalate (DEHT), diisononyl cyclohexanate (DINCH) and 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (TXIB)¹. More specifically, the Chief Inspector asked what uncertainties existed regarding the risk, and how they might be diminished.

Tests conducted at the laboratory of the Food and Consumer Product Safety Authority (VWA) indicate that during the use of toys and child care articles, the three alternative plasticisers can be released in small quantities. From the migration data, the RIVM has calculated the quantities of the three chemicals that may be absorbed by a small child sucking on a plastic object, or by an older child via the skin. Even on the basis of worst-case assumptions, the calculated amounts absorbed would be far below the levels associated with harmful effects. The Office for Risk Assessment therefore concludes that use of the plasticisers DEHT, DINCH and TXIB in toys and child care articles of the kinds examined is safe within certain parameters, which are specified in the recommendations.

The risk assessment does involve a number of uncertainties. One source of uncertainty is the dermal absorption of TXIB. The RIVM has not been able to find any data on this matter in the literature and has therefore estimated the level of such absorption on the basis of properties of the substance. The uncertainty could be diminished by conducting research into the dermal absorption of TXIB. A further source of uncertainty and a matter of some concern is the lack of data on the levels of background exposure to the three substances associated with

¹ See appendix 1 for the abbreviations and CAS numbers.

other applications, such as their use in materials that come into contact with food. Such data are necessary to make an integral safety assessment.

The VWA has established that various alternative plasticisers, besides the three referred to above, are being used in toys and child care articles. Of particular note is the recurring use of nonylphenol, which is classed as potentially detrimental to human fertility or foetal development.

The Office for Risk Assessment makes the following recommendations:

- The Minister of Health, Welfare and Sport (VWS) is advised to set migration limits for the alternative plasticisers assessed in this advice (DEHT, DINCH and TXIB), so that it is clear to manufacturers to what extent the substances may safely be used in toys and child care articles. The scenarios employed by the RIVM may be used to establish what levels of migration of the three substances correspond to an adequate safety margin. In general, a safety margin of a factor of 100 is considered sufficient for chemicals. In Europe, however, the principle is applied that toys may contribute only a fraction of the tolerable exposure to substances. It is therefore desirable that agreement is reached at the European level concerning the application of an extra factor (a percentage of the total tolerable daily intake) for the substances and applications in question.
- In order to set a precise migration limit for TXIB on the basis of internal exposure, it is desirable that dermal absorption of this substance is investigated by its manufacturers. Until reliable dermal absorption data are available, the Minister of VWS is advised to work on the basis of a worst-case assumption.
- The Minister of VWS is advised to draw up a positive list of all the alternative plasticisers, including substances other than the three investigated for this advice, that are suitable for use in toys and child care articles. The list should include substances that have undergone assessment on the basis of toxicity and migration data, and for which migration limits may therefore be defined. Implementation of this recommendation will require agreement to be reached at the European level.
- It would be advantageous for the VWA to collect data on the use of the three assessed alternative plasticisers in other consumer products, particularly products that come into contact with food intended for infants and young children. It may be possible to collaborate with the EFSA on this matter.
- It is desirable that the VWA should continue to monitor the prevalence of nonylphenol use as an alternative plasticiser in toys and child care articles. If further evidence of nonylphenol use is found, it is recommended to perform migration measurements and to use the results in a risk assessment.

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Basis of advice

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Background

There is evidence that phthalates disrupt hormone activity, particularly in young children. Hence, European Directive 2005/84/EC greatly restricts the use of six phthalates as plasticisers in toys and child care articles. The directive is implemented in Dutch law by the Food and Commodities Act Decree on General Chemical Product Safety (1). The Directive sets limits on the concentrations permitted in the relevant products. Since 16 January 2007, toys sold on the Dutch market have had to comply with those limits, as follows:

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- In toys and child care articles, diethylhexyl phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP) shall not be used as substances or as constituents of preparations, at total concentrations of greater than 0,1 per cent by mass of the plasticised material.
- In toys and child care articles which can be placed in the mouth, diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP) shall not be used as substances or as constituents of preparations in total concentrations exceeding 0.1 per cent by mass of the plasticised material. The European Commission has published a guidance document (2) on interpretation of the concept of toys and child care articles 'which can be placed in the mouth'.

Toy makers have since started using a variety of alternative plasticisers. In contrast to the situation with phthalates, there are no statutory limits on the concentrations of these alternative plasticisers that toys and child care articles may contain, although the general requirement that health should not be endangered naturally applies.

In 2007, 2008 and 2009, the VWA systematically sampled toys and child care articles available on the Dutch market. Products were selected for analysis on the basis that they had soft plastic parts, that they were intended for children and that they could be at least partially placed in the mouth (see appendices 2 and 3). Where phthalates were detected, enforcement action, such as the imposition of a sale prohibition, was taken. In its 2008 survey, the VWA also tested the sampled products for the release of three widely used alternative plasticisers: DINCH, TXIB and DEHT. Data on the release of these chemicals are needed to calculate the levels of exposure and thus to make a risk assessment.

The VWA asked the RIVM to assess the risk if children are exposed to the alternative plasticisers through contact with toys and child care articles. To make this risk assessment possible, the RIVM sought toxicological data from the plasticiser producers (see appendix 4).

Issue

The Chief Product Safety Inspector asked the Office for Risk Assessment to address the following questions regarding the use of alternative plasticisers in toys and child care articles:

1. How safe are the encountered alternative plasticisers for use in toys and child care articles, considering the toxicological properties of the substances, the degree of migration determined by the VWA by dynamic measurement, the scenarios for the exposure of children to toys and child care articles and the possibility of exposure from other sources ('background exposure')? When

- making your assessment, please consider the margin of safety that can be expected in the scenarios referred to.
2. What uncertainties does the risk assessment entail (sensitivity analysis) and how could those uncertainties be diminished through research?
 3. Because the requested information is extremely relevant to the formulation of European policy on the safety of toys and child care articles, please address your advice to the Minister of VWS and to the relevant policy directorate.

Scope set by the Office for Risk Assessment

The VWA encountered fifteen different alternative plasticisers. At present, migration data and RIVM risk assessments are available for three substances: DEHT, DINCH and TXIB. The latter three substances are the most commonly encountered plasticisers. Although some adipates, such as DEHA, citrates, such as ATBC, and the substance nonylphenol are also in fairly widespread use, no migration data are yet available for these substances; consequently, it is not currently possible to calculate levels of exposure or to make risk assessments for these substances. The findings of this advice relate only to those substances for which a risk assessment has been performed, i.e. DEHT, DINCH and TXIB. They do not relate to *all* the plasticisers encountered. Particular account should be taken of the fact that nonylphenol was frequently found in products sampled in 2008, since this substance is classified as reprotoxic. In the context of earlier VWA market research, it was concluded that the release of nonylphenol from toys did not represent a hazard to children (3). Nevertheless, it is important to continue monitoring release levels and to reassess the risks if appropriate.

Findings

The RIVM assessed the risk associated with DEHT, DINCH and TXIB on the basis of the maximum levels of migration observed by the VWA. At these maximum levels, the safety margin is substantial. Even in the least favourable case (for TXIB in the dermal contact scenario), the margin is a factor of 170, while any margin of 100 or more is considered as safe. Where the other substances are concerned, the margins are greater than 5000. The analysis was performed on the basis of reasonable worst-case scenarios, involving the oral exposure of a child about ten months old and the dermal exposure of a child about three years old. In the absence of published data, the RIVM estimated the dermal absorption of TXIB to be 50% (taking the substance's molecular weight and lipophilic properties into account). This is a worst-case assumption; the resulting uncertainty could be diminished by performing additional research into the absorption of this substance.

The safety margins referred to above apply to individual products. However, from a risk management perspective, it is pertinent to consider what proportion of total exposure to a substance may be caused by toys and child care articles. The migration limits set for various elements under the European Toy Directive are merely percentages of the tolerable daily intake (TDI) values; in other words, an *allocation factor* is applied to toys.

On the basis of the available data, it is concluded that the three alternative plasticisers DEHT, DINCH and TXIB do not pose a risk in the *individual* products of the types considered. However, if the system applied in the context of the Toys Directive is followed, the limit on the migration of a substance from toys and child care articles should be based not only on the TDI and the usual safety margin (a factor of 100), but also on an allocation factor. If an allocation factor of 10 per

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cent is applied, the minimum safety margin for TXIB (a factor of 170) is too small. It is therefore desirable that the uncertainty regarding dermal absorption of TXIB is addressed. As the RIVM also points out, there is a paucity of toxicological data regarding TXIB. This provides further reason for seeking agreement at the European level regarding the application of an additional factor. By applying the appropriate safety margin and using the exposure scenarios developed by the RIVM, it would then be possible to define a migration limit for each substance, which products would have to meet.

Given that numerous alternative plasticisers are in use, besides the three investigated for this advice, it would make sense to make a further step by compiling a positive list, similar to the list for materials that come into contact with food. A substance should be included on the list only if sufficient data are available to define a migration limit, using the same approach as for DEHT, DINCH and TXIB. Since toys are covered by a European Directive, it is desirable to reach agreement on this strategy at the European level.

The Chief Product Safety Inspector asked the Office to take account of exposure from other sources and thus to produce integral exposure estimates. The RIVM has pointed out that, on the advice of the EFSA, the three investigated plasticisers are allowed in materials that come into contact with food. However, no data are available regarding use of the plasticisers in such materials, regarding the concentrations in which they are used or regarding their migration from such materials to food. It is not therefore possible to provide integral exposure estimates as requested on the basis of the existing data.

Literature

1. Dutch 'Staatscourant' (Government Gazette) 19 September 2006, no. 182, page 20.
2. http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&oc_id=165.
3. *Weekmakers in speelgoed en kinderverzorgingsartikelen* (Plasticisers in toys and child care articles). Groningen: VWA, 7 March 2008. Project number ND072201.

Yours faithfully,

Professor EG Schouten
Director of the Office for Risk Assessment

Appendices:

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Appendices

1. List of abbreviations.
2. *Toepassing alternatieve weekmakers in speelgoed en kinderverzorgingsartikelen. Inventarisatie en migratie-onderzoek* (The Use of Alternative Plasticisers in Toys and Child Care Articles. Inventory and Migration Research). Groningen: VWA, October 2009. Project number: ND082211.
3. *Toepassing weekmakers in speelgoed- en kinderverzorgingsartikelen 2009* (The Use of Plasticisers in Toys and Child Care Articles in 2009). Groningen: VWA, March 2010. Project number: ND092212.
4. Janssen PJCM, Bremmer HJ. Risk assessment non-phthalate plasticizers in toys. Bilthoven: RIVM, 9 November 2009.

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Appendix 1: List of abbreviations

BBP	benzyl butyl phthalate (CAS no. 85-68-7)
DBP	dibutyl phthalate (CAS no. 84-74-2)
DEHP	diethylhexyl phthalate (CAS no. 117-81-7)
DEHT	diethylhexyl terephthalate (CAS no. 6422-86-2)
DIDP	diisodecyl phthalate (CAS no. 26761-40-0)
DINCH	diisononyl cyclohexanate (CAS no. 166412-78-8)
DINP	diisononyl phthalate (CAS no. 28553-12-0)
DNOP	di-n-octyl phthalate (CAS no. 117-84-0)
EFSA	European Food Safety Authority
TDI	tolerable daily intake
TXIB	2,2,4-trimethyl-1,3-pentanediol diisobutyrate (CAS no. 6846-50-0)

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