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Press release

Substitutes for phthalates in toys: no health risk detected for children under three years of age

Today ANSES publishes the results of its expert assessment on the health risks of oral exposure to several chemicals found in plastic toys and materials likely to be mouthed by infants and children under three years of age. For four of the substances studied which are substitutes for phthalates (DINCH, DEHTP, ATBC and TXIB), the Agency did not find any risk to children's health. However, the Agency recommends that risk assessments be conducted systematically for all new substances used for the manufacturing of plastics used in toys and materials for children. ANSES will soon begin an assessment of the combined health risks of exposure by children to certain phthalates classified as toxic for reproduction and will take into account several exposure routes (consumer goods, air, dust, food, etc.).

Several studies based on the observation of the behaviour of children from birth to 36 months of age have shown that plastic is the material most often put in the mouth, followed by textiles. In addition, the majority of toys bought in France are made of plastic. Polyvinyl chloride (PVC) is one of the plastics most widely used in toys and the plasticisers most widely used in PVC are **phthalates**.

Exposure to the many chemicals found in consumer products during critical periods of child development (perinatal period, infancy) is mentioned among the hypotheses for explaining the increase in the incidence of certain diseases such as obesity, neurodevelopmental disorders, effects on the reproductive tract, etc. Children, and in particular those under 36 months of age, are an especially vulnerable population group.

In this context, and following a ban on certain toxic phthalates used in toys, ANSES issued a formal internal request in order to assess the health risks of the substitutes for these substances found in toys and materials made of plastic and used for children under the age of three.

Agency conclusions and recommendations

The Agency's expert assessment concentrated on five substitutes for phthalates: ATBC, DINCH, DEHTP, TXIB and DOIP.

Based on current scientific knowledge, for four of these substances (ATBC, DINCH, DEHTP, TXIB), **the results of ANSES's expert assessment do not show any health risks for children under the age of three.**

For **DOIP**, no risk assessment could be conducted due to a lack of available data (classification currently under examination in the context of the REACH regulation). Therefore, the Agency recommends this substance **not be used** in plastic toys or materials until knowledge on its toxicity can be acquired.

The Agency recommends more generally that the risk assessment for substances found in toys that can be mouthed, and in particular when they are new substances, be conducted before marketing, based on migration testing to provide an estimation of child exposure by the oral route.

Furthermore, the expert assessment conducted by the Agency based on available data, does not account for all the other potential sources of exposure (objects, air, dust, food, etc.). For this reason, ANSES plans to conduct an **assessment of the combined health risks of exposure to certain phthalates in its work programme on endocrine disruptors** which will take into account **several exposure routes**.

In addition, given that substances have been detected whose use is restricted or banned in numerous toys marketed in Europe, **the Agency emphasises the relevance of inspections carried out in the toy sector** in order to avoid the marketing in France of toys that are not compliant with the regulations, and it recommends maintaining at the very least the same level of vigilance.

This work supplements the numerous studies already published on phthalates, including those in the National Endocrine Disruptor Strategy: classification proposals, establishment of toxicity reference values, proposals of various management options within the framework of the European REACH regulations.

How was the study conducted?

Composition tests targeting phthalates and their substitutes were conducted at ANSES's request by the DGCCRF on a sample of toys and materials for children (bibs, teething rings, pacifiers), followed by migration testing in a saliva simulant. These tests were supplemented with measurements of the endocrine activity of the migration fluid. The Agency's risk assessment was conducted on the non-regulated substances that were detected in the framework of these tests.

What were the targeted substances?

The ANSES assessment concentrated on the following five substances used as substitutes for phthalates:

- 1,2-cyclohexane dicarboxylic acid diisonyl ester (DINCH),
- diethylhexyl-terephthalate (DEHTP),
- bis(2-ethylhexyl) isophthalate (DOIP),
- acetyl-tributyl-citrate (ATBC),
- 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (TXIB).

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