

Hexamoll® DINCH

Safe play with the non-phthalate plasticizer
for toys and childcare articles



PLASTICIZERS – FIT FOR PURPOSE

Dolls, inflatables, balls or figurines are examples of toys that are often made with soft-PVC. PVC is a very well-researched plastic which is suitable for toy manufacturing due to its printability, color stability, compatibility and ease of processing among other properties. PVC itself is brittle and plasticizers are chemical compounds that give rigid PVC flexibility.

The type of plasticizer depends on the different requirements of the respective application. Phthalates are used for more than 50 years in flexible PVC applications and are still the most commonly used plasticizers. They are the preferred choice for many technical applications, e.g. wires and cables, roofing membranes or tarpaulins. For BASF, safety in the intended use is a mandatory requirement for the complete product portfolio. Already in 1998, BASF started a research project for an alternative plasticizer with a better toxicological profile than phthalates, making it suitable for use in products that come into close contact with humans. So, BASF developed non-phthalate Hexamoll® DINCH – a plasticizer that has an excellent toxicological profile and offers a well-balanced set of properties. When the European Union restricted phthalates in toys and childcare articles in 1999¹, a children's doll made with Hexamoll® DINCH was one of the first applications in which the plasticizer was used.

HEXAMOLL® DINCH SUCCEEDED PHTHALATES ON THE PLAYGROUND

Based on latest scientific evidence the EU commission reevaluated the phthalate restrictions for toys in 2013 and confirmed to keep them in place². Similar legislations followed worldwide, having an impact on imported toys as well. The European notification system RAPEX shows that phthalate-containing toys entering the European market have been declining in number of detected products³.

What succeeds phthalates in toys? In a market study 252 product samples were collected at retail level in Germany, Switzerland and Austria and it was found that nearly half of the samples contained Hexamoll® DINCH as the principal plasticizer.⁴ It shows broad acceptance of the toy industry for Hexamoll® DINCH as alternative plasticizer succeeding phthalates. Not only due to the success in the toy industry, the production capacity for Hexamoll® DINCH has constantly been increasing to meet market demand. The start-up of the second plant in 2014 doubled BASF's production capacity of Hexamoll® DINCH to 200,000 metric tons per year.

HEXAMOLL® DINCH: TESTED & PROVEN

Depending on annual production volume, REACH (Regulation (EC) No 1907/2006) requires industry to provide mandatory toxicological and ecotoxicological studies according to OECD guidelines and Good Laboratory Practices. BASF has invested more than 7 million Euro in toxicological testing for Hexamoll® DINCH.

A complete regulatory database proves that Hexamoll® DINCH does not show any of these adverse effects: Environmental hazards, peroxisome proliferation, accumulation within the body, organ toxicity, genotoxicity, carcinogenicity or reproductive hazards. The results of the studies have been evaluated by competent authorities worldwide, confirming that Hexamoll® DINCH is safe for its intended use, including highly sensitive applications like food contact, medical devices or toys⁵. The French Competent Authority conducted the so-called Risk Management Option Analysis (RMOA), published by ECHA in January 2016, which concluded that there is no need to initiate further regulatory risk management action⁶.

In general, manufacturers are responsible for the safety of their products and compliance with regulations (via CE marking). Toy manufacturers can rely on global expert knowledge of the competent authorities in the risk assessment of Hexamoll® DINCH confirming its suitability. Products made with Hexamoll® DINCH can fulfill requirements of the EU Toy Safety Directive 2009/48/EC and the relevant European Toy Safety Standards⁷. Because children like to discover the environment with their senses and commonly take toys into their mouths, also food contact approvals are worth to be mentioned: EFSA (European Food Safety Authority) approved Hexamoll® DINCH for use in food contact materials without specific migration limit⁸. This makes Hexamoll® DINCH also suitable for toys for children under three years of age.

CARE IN EVERY TOUCH

While Hexamoll® DINCH is not a hazardous substance, competent authorities investigated plasticizer migration from toys in realistic "play scenarios" to identify the general exposure of children to plasticizers during play time. The National Institute for Public Health and the Environment of the Netherlands (RIVM) considered a scenario of mouthing a toy by a 10-month-old child and skin contact with a toy by a 12-year-old child for 3 hours per day. The risk assessment concluded that the use of Hexamoll® DINCH does not pose any health risk for toy-users⁹. Also the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) published an opinion on health risks of plastic toys in 2016¹⁰. The results based on the exposure scenario for Hexamoll® DINCH do not show a health risk for children aged 0 to 3 years exposed via mouthing of toys.

Children are not only exposed to plasticizers via direct contact with toys but also through other sources. Hexamoll® DINCH is an established general-purpose plasticizer on the market that is used in a broad range of applications, for example in flooring and wallcovering. In this context, BASF actively supports the development and application of human biomonitors methods for exposure monitoring to enable the competent authority to perform solid risk assessments. The analytical methods for determination of urinary metabolites are state of the art research for the industry. The German Federal Environment Agency (Umweltbundesamt) published a study showing that Hexamoll® DINCH metabolites can be found in urine of 98.3% of the general public and that the current exposure of the population is orders of magnitude below the reference value which experts consider safe¹¹.

In 2016, Fromme et al. investigated exposure specifically of children in German daycare centers¹². Plasticizer levels in indoor air and dust samples from 63 daycare centers were measured and analysis of urine samples from 208 children for the presence of Hexamoll® DINCH metabolites conducted. The maximum actual intake reached only 1% (9.8 µg per kg bodyweight) of the reference value (1000 µg per kg bodyweight) which was defined as tolerable daily intake by EFSA. The median intake calculated is 0.5 µg per kilogram bodyweight per day (=0.05%); no risk.

Thus, using Hexamoll® DINCH for the production of toys can provide peace of mind to both, the manufactures and parents.

REFERENCES

¹ EU Commission Decision 1999/815/EC:

DEHP, DBP, BBP shall not be used as substance or mixture in concentrations greater than 0.1% by weight of the plasticized material, in toys and childcare articles. DINP, DIDP and DnOP are restricted for use in toys and childcare articles that can be placed in mouth.

² REACH Regulation (EC) No 1907/2006,

Annex XVII (52a). Inclusion of DINP, DIDP and DnOP: Shall not be used as substance or in mixtures, in concentrations greater than 0.1% by weight of plasticizer material, in toys and childcare articles which can be placed in mouth.

³ Rapid-Alert System (RAPEX)

for dangerous non-food products facilitates the information exchange between Member States and the European Commission on the measures taken to prevent or restrict the marketing or use of consumer products posing a serious risk to consumer health and safety. In 2016 RAPEX listed 128 results for phthalate-containing toys, compared to 170 matches the year before.

⁴ Biedermann-Brem et al. (2008).

Plasticizers in Toys and Childcare Products: What Succeeds Phthalates? Market Survey 2007. *Chromatographia* 2008, 68, 227-234.

⁵ Selection of evaluations by competent authorities:

EU: EFSA and SCENIHR; Germany: UBA, BfR, BAuA; Switzerland: BAG; The Netherlands: RIVM, France: ANSES; Denmark: EPA; Sweden: KEMI; USA: NSF; Canada: Health Canada; Australia: NICNAS; China: Chinese FDA; Korea: Korean FDA; Japan: PMDA, MHLW.

⁶ ANSES (2016):

Analysis of the most appropriate risk management option (RMOA). Published by ECHA.

⁷ European Toy Safety Standards,

especially EN 71-3 (Migration of certain elements), 71-5 (Chemical toys other than experimental sets), 71-9 (Requirements concerning organic chemical compounds).

⁸ EFSA Regulation (EU) No 10/2011

on substances in contact with food: Hexamoll® DINCH is listed in FCM 775: The overall migration limit applies, i.e. 60 mg/ kg food.

⁹ RIVM (2009).

Risk assessment non-phthalate plasticizers in toys.

¹⁰ ANSES (2016).

Opinion on "plastic toys and children's equipment intended for children under three years of age."

¹¹ Umweltbundesamt (2014).

Stoffmonographie für 1,2-Cyclohexandicarbonsäure-di-isononyl-ester (Hexamoll® DINCH) - HBM-Werte für die Summe der Metabolite Cyclohexan-1,2-dicarbonsäure-mono-hydroxyisononyl-ester (OH-MINCH) und Cyclohexan-1,2-dicarbonsäure-mono-carboxy-isoocetyl-ester (cx-MINCH) im Urin von Erwachsenen und Kindern. Stellungnahme der Kommission „Human Biomonitoring“ des Umweltbundesamtes. *Bundesgesundheitsblatt*, 2014, 57: 1451-1461.

¹² Fromme et al. (2016).

Non-phthalate plasticizer in German daycare centers and human biomonitors of DINCH metabolites in children attending the centers. *International Journal of Hygiene and Environmental Health* 219 (2016), 33-39.



FREQUENTLY ASKED QUESTIONS

1. For which applications is Hexamoll® DINCH used?

Hexamoll® DINCH is widely used in a broad range of applications like wallpaper, flooring, sports equipment, apparel, food packaging, toys and medical devices. Hexamoll® DINCH exhibits excellent blood compatibility and in 2013 was awarded the SolVin Award Special Prize for successful substitution of the phthalate DEHP in blood bags.

2. Who are your customers in the toy industry?

Toy manufacturers using Hexamoll® DINCH are located worldwide across the entire value chain. Leading brand owners in the toy industry trust Hexamoll® DINCH for its high quality and performance. Take a closer look at the packaging of inflatables, figurines or dolls and you may be able to discover the Hexamoll® DINCH logo – Care in every touch.

3. What is the difference between Hexamoll® DINCH and phthalates?

Hexamoll® DINCH is not a phthalate but a cyclohexanoate and a non-aromatic plasticizer with a completely different structure (three-dimensional ring) belonging to a different chemical structural class. The maximum residual concentration of phthalates in the current product specification is 0.01% and BASF conducts constant lab analytics and pre-loading inspections to deliver high quality products to our customers.

4. What makes Hexamoll® DINCH a preferred plasticizer for toy manufacturing?

Hexamoll® DINCH is an intensively researched product. BASF conducted numerous tests to demonstrate that Hexamoll® DINCH has an excellent toxicological profile. Evaluations of the studies and risk assessments by competent authorities conclude that there is no risk associated to exposure from toys made with Hexamoll® DINCH.

5. Can Hexamoll® DINCH substitute other plasticizers in toy manufacturing?

Hexamoll® DINCH can be processed on existing machinery, requiring only minor adjustments in formulation and process parameters. It can be used in the common PVC production processes. Good rotomoldability and lower viscosity than other alternatives like Terephthalates (DOTP) or Citrates (ATBC) make it stand out.

6. Do toys made with Hexamoll® DINCH comply with regulations globally?

CE-marked toys have been available on the market for over a decade. The toxicological profile and extensive risk assessments have led to worldwide approvals. Toys made with Hexamoll® DINCH can fulfill the requirements of the following regulations:

- EU Regulation (EC) No 1907/2006 (REACH):
No further risk measures needed
- EU Toy Safety Directive 2009/48/EC
- EU Toy Standards EN 71-3, EN 71-5, EN 71-9
- US-CPSC toy safety specification ASTM F963

7. Where is Hexamoll® DINCH manufactured?

Hexamoll® DINCH is produced in Ludwigshafen, Germany in two separately operating plants with a total capacity of 200,000 metric tons per year. It is available globally and the technical centers in Europe, Asia and North America are ready to support in any technical question.

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