

Preliminary estimation of undesired substances in diapers

BfR Communication No. 005/2019 of 01 March 2019

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has published a comprehensive report on hazardous substances in disposable panty diapers on 23 January 2019 entitled “Sécurité des couches pour bébé”.

Here, the German Federal Institute for Risk Assessment (BfR) evaluated the results of this report. However, a complete and conclusive assessment is currently impossible, as important detailed information of technical nature is not available to the BfR.

The report “Sécurité des couches pour bébé”, published by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), deals with hazardous substances in disposable panty diapers. In the following paragraphs, the BfR provides a preliminary estimation of the levels of contaminants and aromatic substances measured in the diapers. The BfR cannot currently make a detailed estimation of the other substances mentioned in the report for which ANSES has prepared a health assessment.

Estimation of the contaminants detected in diapers

The detection of ubiquitous contaminants such as dioxins and furans, dioxin-like polychlorinated biphenyls (dl-PCB) and polycyclic aromatic hydrocarbons (PAH) in the trace range is to be expected, as very small quantities of each substance can be ubiquitously detected with modern analytical methods. This also applies to residues of substances used in the manufacture of diapers or in the production of raw materials such as cotton (e.g. glyphosate). Yet, the detection of these substances does not necessarily involve a health risk.

ANSES used four different test scenarios to examine potentially health-damaging substances in diapers. These scenarios serve to estimate the exposure in terms of skin contacts with the substances under consideration. In one scenario, for example, the substances were extracted from pulverised diaper parts using an organic solvent. In another scenario, the diapers were prepared with a urine simulant (artificial urine) in order to determine the transfer (migration) of the substances to the artificial urine. The approach chosen by ANSES serves as an approximation method to estimate maximum exposure. To what extent this estimation involves uncertainty cannot currently be estimated by the BfR, as some of the necessary information is still missing.

Because different test and/or exposure scenarios are used, the report sometimes produces different qualitative risk statements (no risk vs. possible risk) for one and the same substance. This is partly attributable to the fact that, depending on the scenario, worst case (conservative) assumptions of varying severity were made through the intentional (risk-covering) overestimation of exposure.

Mainly conservative assumptions are used as the basis of the exposure parameters in both the worst case as well as the refined exposure estimation. It is assumed, for example, that every single diaper worn in the course of infancy is contaminated with the highest concentration determined for each substance. The method of assuming conservative values for the exposure parameters is common and also used by the BfR when assessing the health risks of consumer products. The purpose of this is to ensure that a possible health risk will not be underestimated. The result of this, however, is the tendency of an overestimation of exposure and therefore of the risk too. The probability of the occurrence of an undesired effect is

therefore lower in reality. Risks established in this way therefore might indicate a need for research and potential action (e.g. under REACH).

According to the exposure estimation in the ANSES report, the latest available knowledge indicates that the analysis values for glyphosate and/or the metabolite aminomethylphosphonic acid (AMPA) do not constitute a health risk.

Estimation of contact allergenic aromatic substances detected in diapers

Potentially contact allergenic aromatic substances were detected in one of the 19 diaper products examined (ANSES, 2019). Perfumes and aromatic substances are added to diapers during the manufacturing process for the purpose of enhancing the “aesthetics” (Kosemund et al., 2009; Rai et al., 2009), i.e. the appeal of the product. According to the information of the manufacturers, perfume is commonly used in diapers or certain parts thereof in such a way that no direct skin contact occurs (Rai et al., 2009). As the theoretical possibility of indirect skin contact still exists as a result of the backflow of urine from the absorbent diaper core (Rai et al., 2009), this was taken into consideration by ANSES. The BfR is not currently aware of any experimental examinations that go beyond this.

Contact allergenic aromatic substances entail the potential of sensitisation. This means that an allergy can develop if the skin comes in contact with substances of this kind. Once a person has become sensitised, it has to be assumed that the allergy will last for a lifetime and that health impediments are possible. The subsequent formation of contact eczemas can only then be prevented by avoiding contact with the allergen.

No specific legal provisions exist for the use of contact allergenic aromatic substances in disposable diapers. There are no bans on use or any declaration obligations (unlike cosmetic products). If the aromatic substances used in diapers (to an allergologically relevant extent) can get into contact with the skin, the aromatic substances that are banned from use in cosmetic products, or which have a high sensitisation potential, should not be used in the opinion of the BfR.

Regulations on diapers

The basic rule is that responsibility for compliance with legal provisions on the health safety of products lies initially with the manufacturer or distributor. Monitoring of legal regulations in Germany is the responsibility of the Federal States (“Länder”). In addition to this, the BfR published tips on the assessment of intimate hygiene products (BfR, 1996) in which it recommends that specifications should be established for the raw materials used in the manufacture of panty diapers and diaper liners.

More information on the subject of diapers at the BfR website

https://www.bfr.bund.de/de/a-z_index/windeln-4813.html (in german)



BfR “Opinions App”

References

Agence nationale de sécurité sanitaire alimentation, environnement, travail ANSES (2019) Sécurité des couches pour bébé – avis révisé de l'Anses Rapport d'expertise collective; <https://www.anses.fr/fr/system/files/CONSO2017SA0019Ra.pdf> (aufgerufen am 01.03.2019)

Bedarfsgegenständeverordnung (BedGgStV) in der Fassung der Bekanntmachung vom 23. Dezember 1997 (BGBl. 1998 I S. 5), die zuletzt durch Artikel 2 Absatz 1 des Gesetzes vom 15. Februar 2016 (BGBl. I S. 198) geändert worden ist

Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin BgVV (2000) BgVV Stellungnahme zu TBT und zinnorganischen Verbindungen in Höschenwindeln; https://www.bfr.bund.de/cm/343/tbt_windeln.pdf (aufgerufen am 01.03.2019)

Bundesinstitut für Risikobewertung BfR (1996) Hinweise zur Beurteilung von Intimhygienezeugnissen. Bundesgesundheitsblatt 39: 124; <https://bfr.ble.de/kse/faces/resources/INTDEUTSCH.pdf> (aufgerufen am 01.03.2019)

Verordnung (EG) Nr. 1223/2009 des Europäischen Parlaments und des Rates vom 30. November 2009 über kosmetische Mittel (ABl. L 342 vom 22.12.2009, S. 59), zuletzt geändert durch Verordnung (EU) 2018/978 der Kommission vom 9. Juli 2018 (ABl. L 176 vom 12.07.2018, S. 3), zuletzt berichtigt durch ABl. L 183 vom 19.7.2018, S. 27

Kosemund K, Schlatter H, Ochsenhirt JL, Krause EL, Marsman DS, Erasala GN (2009) Safety evaluation of superabsorbent baby diapers. Regulatory Toxicology and Pharmacology 53: 81-89; doi: 10.1016/j.yrtph.2008.10.005

Lebensmittel- und Futtermittelgesetzbuch (LFGB) in der Fassung der Bekanntmachung vom 3. Juni 2013 (BGBl. I S. 1426), das zuletzt durch Artikel 1 des Gesetzes vom 30. Juni 2017 (BGBl. I S. 2147) geändert worden ist

Rai P, Lee B, Liu T, Yuhui Q, Krause E, Marsman DS, Felter S (2009) Safety evaluation of disposable baby diapers using principles of quantitative risk assessment. Journal of Toxicology and Environmental Health, Part A 72 (21-22): 1262-1271

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.