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## **British Report on Hypospadias and Biocides Based on Limited Study with Possible “Chance Associations”**

Experts Continue to Recommend DEET

“A recently published retrospective epidemiological review by Dugas, et al of hypospadias in a small population of boys in England used questionable methods to suggest that there is an association with the occurrence of this fairly common birth defect and the use of insect repellents by pregnant women,” said Susan Little, director of the DEET Education Program, Washington, D.C. “There is nothing in the scientific literature in the past 30 years or in extensive tests in animals of different species that shows that DEET is responsible for this or any other birth defects, even when the pregnant animals were given doses far higher (as a percentage of their body weight) than humans could ever be exposed to.”

In the study, both DEET and permethrin are mentioned as potential repellent products that might have been used. However, the data collected in the study questionnaire were not detailed to a level that would support that assertion. DEET is formulated for use on skin and repels but does not kill insects. Permethrin is NEVER to be applied to the skin and kills insects.

Little noted that the robust therapeutic trial study design of McGready, et al (*American Journal of Tropical Medicine and Hygiene, 2001*), is a far more reliable indicator of DEET’s impact on pregnant women and their babies than the British retrospective study by Dugas, et al. In that peer-reviewed study of nearly 900 pregnant women and their babies, the authors concluded that DEET is safe to use in pregnancy. The McGready research, which the Dugas team cites in its report, included blood tests administered to the women and to their newborn children. The infants were assessed for illness, birth defects and developmental delays. No adverse effects were found among

the babies whose mothers used DEET while pregnant. The authors concluded, “This study suggests that DEET is safe in the second and third trimesters of pregnancy.”

The Dugas et al study on hypospadias was published in *Occupational and Environmental Medicine*. It

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relied on questionnaires to assess exposure, rather than gathering data by direct measurement. Even more critically, the mothers were asked to recall during a phone interview conducted four to seven years afterwards whether or not they had used agricultural/residential pesticides, insecticides or repellents. The researchers did not obtain information on the type of repellent used, the product ingredients or the amounts applied to the skin, or any of the other compounds to which the women may have been exposed.

Experts suggest that hypospadias occurs in every 100-250 male births and there is a likely a genetic factor at play, because approximately 20% of other male family members are also affected. Dugas et al list other factors that are suspected, as well, noting it is one of the most common congenital anomalies. Hairspray, smoking, folates and other factors are noted as possibly being involved.

“In short, it is misleading to insinuate a causal relationship between insect repellents and hypospadias,” Little added. “With a common anomaly like hypospadias, if one makes enough comparisons, one will ultimately get statistically significant associations simply by chance. This has little to do with reality or causality. It’s just statistics.”

This fact is reflected in the British researchers admission that their study’s methodology is limited and the results possibly “reflect chance associations.” They wrote, “...The analyses were not adjusted for multiple testing, so it is possible that our positive findings for insect repellents and total biocide score reflect chance associations.”

This limitation was also addressed by Prof. Anthony Dayan, former director of toxicology at St. Bart’s Hospital Medical College in London. He said, “As the authors themselves note, their finding is only tentative and preliminary, and, as is common in such surveys at a distance, the participation rate of patients was low and some of the essential controls were missing.”

Professor Alan Boobis, director of health toxicology at Imperial College, London, said, “As the authors themselves point out, there are a number of caveats that need to be borne in mind.

“Insect repellents such as DEET have a valuable role to play,” Boobis said. “It would be premature to take action now based on this information.”

As the world’s most widely used insect repellent, DEET has been extensively studied for more than 50 years. Animal studies have shown that DEET is not a carcinogen, teratogen or mutagen.

“The thorough research done around the world on DEET for decades, combined with the more than 50 years of consumer use, paint a very clear picture of its reliability,” Little said. “This review of hypospadias is in stark contrast to the solid scientific record on DEET and the suggested link to this condition in newborns is questionable, at best.”

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### Other Experts’ Opinions about DEET

Experts have routinely commented on the use of DEET-based repellents, Little said, citing the following:

“...DEET has been used for 50 years with a tiny number of reported adverse events, many of which had a history of excessive or inappropriate use of repellent. ... Its toxicology has been more closely scrutinized than any other repellent, but it has been deemed safe for human use, including use on children and pregnant women.”

Mustapha Debboun, Ph.D., BCE; Stephen P. Frances, Ph.D., and Daniel Strickman Ph.D. *Insect Repellents—Principles, Methods and Uses*, CRC Press, 2007.

“Repellents containing DEET are very safe when used according to directions. No serious illness has been linked to use of DEET in children when used according to manufacturer’s recommendations.”

Insect Repellent Use & Safety,

[www.cdc.gov/ncidod/dvbid/westnile/WNVmyths.htm](http://www.cdc.gov/ncidod/dvbid/westnile/WNVmyths.htm)

“DEET has a remarkable safety profile after 40 years of use and nearly 8 billion human applications. When applied with common sense, DEET-based repellents can be expected to

provide a safe as well as long-lasting repellent effect. Despite the substantial attention paid by the lay press every year to the safety of DEET, this repellent has been subjected to more scientific and toxicological scrutiny than any other repellent substance."

Mark S. Fradin, M.D., and Jonathan F. Day, Ph.D., *New England Journal of Medicine*, 2002

"Part of our confidence in the safety of DEET is based on the extreme rarity of negative effects from its application."

Daniel Strickman Ph.D., Stephen P. Frances, Ph.D., and Mustapha Debboun, Ph.D., BCE, *Prevention of Bug Bites, Stings and Disease*, Oxford Press, 2009.

### More Information

The DEET Education Program has been educating consumers and medical professionals about insect repellents and other measures to prevent insect and tick bites, along with the diseases these pests sometimes carry, for more than 15 years. "DEET is the 'gold standard' repellent and is the most widely-used active ingredient in repellent products worldwide. It has been used reliably

by consumers for more

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than 50 years. The body of evidence supporting its use is enormous," Little said.

The DEET Education Program provides individualized answers to questions within 24 hours on weekdays and 48 hours on weekends and holidays by calling toll-free 888-No-Bites (888-662-4837). Questions can be submitted via [www.deetonline.org](http://www.deetonline.org). It operates under the auspices of the Consumer Specialty Products Association, Washington, D.C., and is sponsored by Clariant Corp., McLaughlin Gormley King Co., S.C. Johnson, 3M Company and Vertellus Health and Specialties Inc.