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Environment, Health and Safety Committee Note on: Why Do We Worry About Parabens?

WHAT ARE THEY?

Parabens are esters of *para*-hydroxybenzoic acid. Common examples include methylparaben (E218), ethylparaben (E214) and propylparaben (E216). Less common types include benzylparaben and isobutylparaben. All commercially used parabens are made synthetically - by the esterification of *para*-hydroxybenzoic acid with the appropriate alcohol - although some are identical to those found in nature, such as in blueberries, prunes and cinnamon.

USES

Parabens are the most widely used preservatives in cosmetics and personal care products which they protect from deterioration during storage and use. Many such products contain two or more parabens as part of their preservative system, as they work in a synergistic manner, especially with phenoxyethanol. They are present (at a maximum concentration of 0.4 %) in over 90% of cosmetics products on the market - such as, deodorants, skin creams, shampoos, moisturisers, shaving gels and toothpaste. As preservatives in cosmetics are required to be declared on the product label, consumers can readily find out which products contain which parabens.

In the EU, methyl, ethyl and propyl parabens are permitted (by Directive 95/2/EC) as preservatives in small quantities (up to 300 mg/kg) in four categories of processed foods, such as in the surface treatment of dried meat products, jelly coatings of meat products such as paté, in confectionery (excluding chocolate) and in liquid dietary food supplements.

They are also used industrially in oils, fats, shoe polishes, textiles and glues.

HOW DO THEY WORK?

Parabens are colourless and odourless. They have no taste, do not discolour and are practically pH neutral. Although most effective against moulds and yeasts, they exert a broad spectrum of antimicrobial activity over a wide pH range. They prevent such degradation in cosmetic products, especially in the moist, warm atmosphere of the average domestic bathroom, and thus prolong their shelf-life. When used in skin care products, they are readily absorbed through the skin, metabolised and excreted by the body. They are absorbed into the bloodstream rather than through the gastrointestinal tract.

BENEFITS

They are extremely effective preservatives and cost little to produce. They have been used as such in cosmetics since the 1920s and have a far lower incidence of health effects - such as allergic skin reactions – than that associated with formaldehyde-releasing preservatives which they replaced decades ago.

RISKS DURING MANUFACTURE AND USE

There do not appear to be any particular health risks to people involved in the manufacture of parabens and their formulation into consumer products, so long as the provisions of the Control of Substances Hazardous to Health (COSHH) Regulations are properly applied, particularly in the carrying out of risk assessments and control of potential exposure to workers.

This Note was produced by a Working Party of the Environment, Health and Safety Committee [EHSC] of the Royal Society of Chemistry.

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For many years, parabens have been regarded as safe as they have low toxicity at the concentrations used. They are approved for use in the EU (by Cosmetics Directive 76/768/EEC) at a concentration limit of 0.4% in cosmetic products. In 2005, the European Commission's Scientific Committee on Consumer Products (SCCP) concluded that the use of methyl- and ethylparaben is safe in cosmetics, as regulated.

The main issue relates to products, as creams and facial lotions for application to the skin. Although some people may suffer allergic reactions - causing skin irritation, contact dermatitis and rosacea - examples of such reactions or sensitivity are extremely rare, when applied to normal skin. However, use on broken or damaged skin may result in sensitisation. Ingestion is also a significant route of exposure from such products, since people frequently and often transfer materials from hand to mouth. The recommended Acceptable Daily Intake (ADI) for combined methyl and ethyl parabens is 10 mg/kg body weight/day.

Another issue is a possible link with breast cancer, where some research has found very low concentrations of parabens in samples of breast tumours from breast cancer patients, which may have migrated from deodorants applied to the underarms.

However, the USA Food & Drug Administration (FDA) has concluded that this research does not show that parabens cause cancer or that they are harmful in any way. Their medical and toxicological experts have classified methyl- and ethylparabens as Generally Regarded As Safe (GRAS) for use in food (at concentrations up to 0.1 %) and that there is no reason for consumers to be concerned about the use of parabens in cosmetics.

The USA National Cancer Institute believes that there is no decisive evidence that parabens in such products are linked to breast cancer.

The Cancer Research UK has also said there is no evidence that underarm deodorants are responsible for any increased risk of breast cancer and that reports on this have not shown any causative results. Any possible increased incidence of breast cancer can readily be attributed to many other factors.

Parabens have also been shown to be very weak mimics of oestrogen - a female hormone involved in the development of breast cancer - calling for their health risks to be investigated further.

ALTERNATIVES

In view of the increased attention being paid to the possible health risks associated with parabens, some companies are now offering cosmetics and toiletries - particularly deodorants - which do not contain parabens although they may be more expensive. One alternative is Grapefruit Seed Extract (GSE), a concentrated extract of the seeds and pulp of grapefruit, which is claimed to have antimicrobial and antiviral properties. However, it is not clear whether this and various other naturally-derived preservatives have been properly tested for their efficacy, raising concerns about their safety and the shelf-life of products containing these substances.

UNCERTAINTIES

Although the long-term health effects of parabens have not been exhaustively characterised, some research findings have raised questions which some scientists feel merit further investigation, despite the long history of favourable experience with their use.

Note was prepared by a Working Party of the RSC Environment, Health and Safety Committee.

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