Session 1

Background

Preservatives are chemicals that are commonly added to food or general household products such as toiletries and pharmaceuticals in order to increase their shelf lives.

Preservatives can act as antimicrobials, antioxidants, or both. As antimicrobials, they prevent the growth of moulds, yeasts and bacteria. As antioxidants, they prevent oxidation reactions which result in e.g. the degradation of polyunsaturated fatty acids (rancidity).

Names and structures of common preservative chemicals:

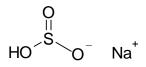
t-butylhydroxyanisol (E320)

t-butylhydroxytoluene (E321)

HO

Sodium metabisulfite

HO



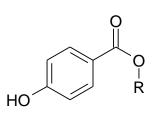


Sulphur Dioxide

<u>Parabens</u>

Alkyl esters of para-hydroxybenzoic acid, more commonly named Parabens, have long been used as preservatives in a wide range of both cosmetic and pharmaceutical formulations. Their bactericidal and fungicidal properties combined with their high solubility in water and ease of manufacturing explains why parabens are used as effective preservatives in many types of household products. They can be found in shampoos, commercial moisturizers. shaving aels. cleansing aels. personal lubricants. topical/parenteral pharmaceuticals, spray tanning solution and toothpaste. Parabens are also widely used in the food industry, enhancing the shelf life of several processed foodstuffs.

General structure of Parabens



Methyl Paraben:	R=CH₃
Ethyl Paraben:	$R=C_2H_5$
Propyl Paraben:	$R=C_3H_7$
Butyl Paraben:	$R=C_4H_9$

The Paraben Controversy

Previously, UK researchers (Harvey and Darbre; 2004) showed that parabens could be detected in human breast tumours and proposed a link between underarm cosmetics (which contain parabens) and cancer. These researchers also demonstrated that parabens exhibit a weak estrogenic activity. The publication of these results initiated a huge scientific debate leading to an unresolved controversy. As a result, there is currently worldwide concern over the use of parabens in common household products such as cosmetics and skincare products.

Several governmental agencies (including the <u>European Community</u>) have carefully evaluated the available scientific data on the safety aspects of parabens. The general view is that the estrogenic effects caused by the doses of parabens received from consumer products are likely to be insignificant and that, in light of the current scientific literature, parabens are practically non-toxic, not carcinogenic, not genotoxic or co-carcinogenic, and not teratogenic. However, the on-going nature of this debate has resulted in the removal of parabens from numerous products and these are often referred to as "paraben-free".

Parabens - The position of the EU

The following extract was obtained from the COUNCIL DIRECTIVE (76/768/EEC) of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products:

Page 5:

"Article 4

1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

(a) substances listed in Annex II;

(b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;

(c) colouring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

(d) colouring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

(e) preservatives other than those listed in Annex VI, Part 1;

(f) **preservatives** listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product"

Parabens (4-hydroxybenzoic acid esters) are listed in annex VI (page 110). Annex VI also details the limits and condition of use of parabens as preservatives in cosmetic products.

Aims and objectives of current investigation

The aims of this investigation are to determine the identities and quantities of individual parabens in a range of commercial household products, and to compare the results obtained for different products. Over a series of sessions, you will:

- Design an experimental procedure to extract paraben(s) from various household products.
- Determine which parabens are present in each of the products.
- Quantify the amounts of each paraben present.
- Evaluate the accuracy of any packaging information
- Assess the paraben content against EU legislation.
- Evaluate the different experimental procedures.

The style of these laboratory sessions may be somewhat different to that which you have experienced before. For example, in the first session, you will be discussing some aspects of experimental design before implementing an agreed procedure. The results of this first experiment will then be discussed and used to plan for a second, possibly improved method to be carried out in the next session. The investigation will also give you the opportunity to use some laboratory skills/techniques for which you may already have some experience (e.g. HPLC, GC).

This problem-based approach should enable you to develop your laboratory skills and your understanding of the underlying chemistry.

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Title	Parabens in household products
Classification	Laboratory Manuals - Chemistry
Keywords	ukoer, parabens, chemistry, analytical, GC
Description	Individual lab sheets - Student
Creative Commons Licence (url)	http://creativecommons.org/licenses/by-nc-sa/2.0/uk/
Language	English
File size	120 kB
File format	pdf