

PARABENS AS PRESERVATIVES

UENO FINE CHEMICALS INDUSTRY LTD.

WHAT ARE PARABENS?

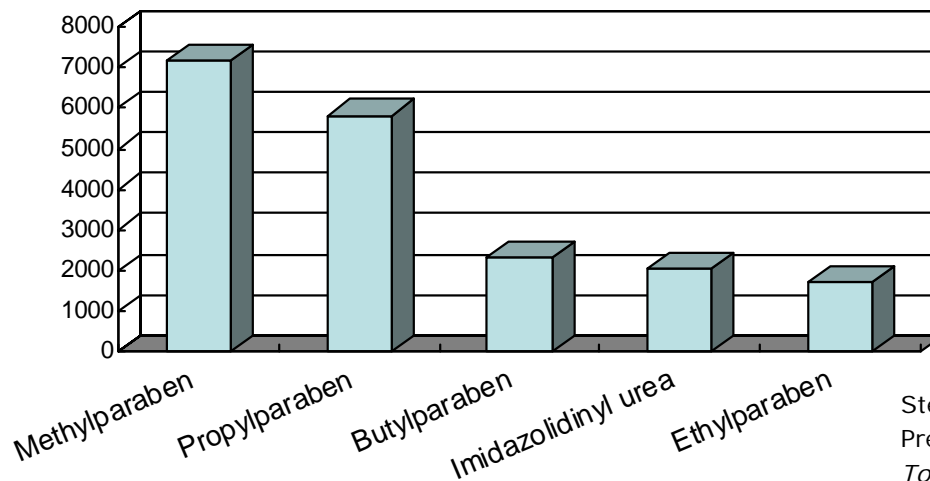
Preservatives are added to food, cosmetic, and pharmaceutical products to prevent decomposition due to bacterial action.

Among preservatives, **the Parabens are the most commonly used** because of their low toxicity to humans and their effective antimicrobial activity, especially against molds and yeasts.

The Parabens are esters of *p*-hydroxybenzoic acid.

The Parabens are Methylparaben, Ethylparaben, Propylparaben, utylparaben.

Frequency use of preservatives in cosmetic formulations in 2003



Steinberg, D.C., Frequency of Use of Preservatives 2003, *Cosmetics & Toiletries*, **119**(1), 55-58 (2004)

PARABENS'

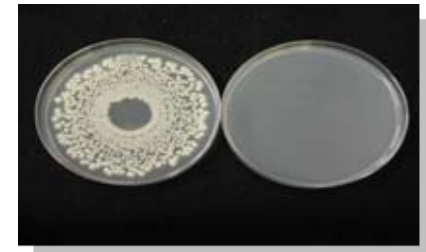
MICROBACTERIAL EFFECTS



Escherichia coli IFO 3972 :
METHYL+PROPYL
PARABEN (2:1) 0.1%



Staphylococcus aureus
IFO 13276 :
METHYL+PROPYL PARABEN
(2:1) 0.1%



Candida albicans ATCC 10231 :
METHYL + PROPYL PARABEN
(2:1) 0.05%



Pseudomonas aeruginosa IFO
13275 :
METHYL+PROPYL PARABEN
(2:1) 0.2%



Aspergillus niger ATCC 16404 :
METHYL+PROPYL PARABEN
(2:1) 0.05%

Left : without Parabens
Right :with Parabens

PARABENS'

MICROBACTERIAL EFFECTS

Minimum Inhibitory Concentration of Parabens (%)

Microorganism		MIC			
		MP	EP	PP	BP
Molds	<i>Aspergillus niger</i> ATCC 10254	0.1	0.04	0.02	0.02
	<i>Penicillium digitatum</i> ATCC 10030	0.05	0.025	0.0063	0.0032
Yeasts	<i>Candida albicans</i> ATCC 10331	0.1	0.1	0.0125	0.0125
	<i>Saccharomyces cerevisiae</i> ATCC 9763	0.1	0.05	0.0125	0.0063
Bacteria	<i>Bacillus subtilis</i> ATCC 6633	0.2	0.1	0.025	0.0125
	<i>Bacillus cereus var. mycoides</i> ATCC 6462	0.2	0.1	0.0125	0.0063

MP:Methylparaben

EP:Ethylparaben

PP:Propylparaben

BP:Butylparaben

Aalto,T.R., Firman,M.C., Rigler,N.E.,
p-Hydroxybenzoic acid esters as preservatives I ,
J.Am.Pharm.Assoc.Sci.Ed.,**42**,449-457 (1953)

USES IN COSMETICS

Parabens have been successfully used in cosmetics for more than 80 years.

The use of Paraben, alone or in combination with other compounds, is well suited for the preservation of cosmetics.

In most cosmetics, Parabens are used at very low levels ranging from 0.01 to 0.3%.

<http://www.cfsan.fda.gov/~dms/cos-para.html>

U.S. Food and Drug Administration, August, 2006



The product containing Parabens may be used on an occasional or a consistent basis and their use may extend product life.

USES IN FOODS



Under FDA regulation, **Methylparaben and Propylparaben are generally recognized as safe (GRAS)** when used as chemical preservatives in foods, with a use limit of 0.1% for each.

They are used in processed vegetables, baked goods, fats and oils, seasonings, sugar substitutes, and frozen dairy products in concentrations up to 0.1%.

Elder, R.L. , *et al.*, Final Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, and Butylparaben, *Journal of The American College of Toxicology*, **3**(5), 147-209 (1984)

USES IN PHARMACEUTICALS

Parabens were first used in pharmaceutical products in 1924. Since then, they have been incorporated as preservatives in a variety of pharmaceutical formulations.

Combinations of Parabens are more effective as preservatives than individual esters.



PARABEN'S SAFETY

The safety has been proven by various studies (*in vivo* tests) as stated below :

- acute chronic and subchronic toxicity studies
- carcinogenesis studies
- reproduction toxicity studies
- absorbing, metabolizing, and excreting studies
- skin stimulating test
- photo-contactsensitization and phototoxicity studies

In 1974, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommended the group Acceptable Daily Intake (ADI) for the methyl-, ethyl-, propyl-esters of *p*-hydroxybenzoic acid as 0-10 mg/kg body weight/day (JECFA,1974).

	Methylparaben	Propylparaben
Acute Toxicity (LD ₅₀)	2-8g/kg<	2-8g/kg<
Mutagenicity(Bacterium)	Negative	Negative
ADI	0-10mg/kg	0-10mg/kg

TOPICS —Parabens, underarm cosmetics, and breast cancer(1)

The link between the use of underarm cosmetics and breast cancer has been promoted through a number of publications by Dr.Darbre and Dr.Harvey.

About this problem;

Dr.Darbre et al. answered the question from the consultants of the Cosmetic, Toiletry, and Fragrance Association (CTFA), 'nowhere in the manuscript was any claim made that the presence of parabens had caused the breast cancer, indeed the measurement of a compound in a tissue cannot provide evidence of causality.'

Golden,R., Gandy,J., Letters to the Editor, *Journal of Applied Toxicology*, **24**,297-306 (2004)

TOPICS —Parabens, underarm cosmetics, and breast cancer(2)

It is the opinion of the Scientific Committee on Consumer Products of European Commission (SCCP) that, in the light of the present knowledge, there is no evidence of demonstrable risk for the development of breast cancer caused by the use of paraben-containing underarm cosmetics.

SCCP/0874/05, Opinion of the Scientific Committee on Consumer Products on Parabens, underarm cosmetics and breast cancer, adopted by written procedure on 28 January 2005

The Cosmetic Ingredient Review (CIR) Expert Panel concluded that Parabens are safe as used in cosmetics in the safety assessment.

Final Report of the Cosmetic Ingredient Review Expert Panel, Amended Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, and Benzylparaben, June 13, 2006

CONCLUSION

The Parabens are the most commonly used preservatives because of their low toxicity to humans and their effective antimicrobial activity, especially against molds and yeasts.

Parabens have been studied by a lot of researchers and its safety has been confirmed from numerous test results.

Parabens are observed and approved by official organizations all over the world.

Therefore, we can conclude people can safely use products that contain parabens.