

# **PARABENS AS PRESERVATIVES**

**UENO FINE CHEMICALS INDUSTRY LTD.**

# WHAT ARE PARABENS?

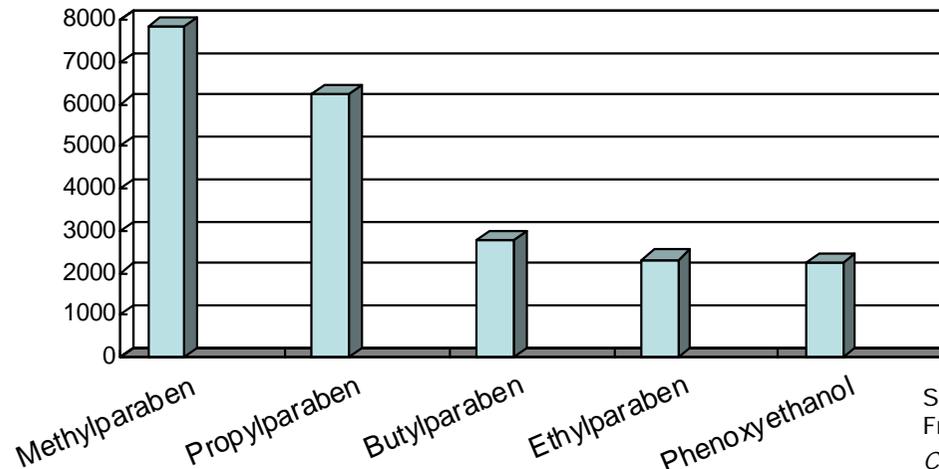
Preservatives are added to food, cosmetic, and pharmaceutical products to prevent decomposition due to bacterial action.

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 2005



Steinberg, D.C., 2005 Preservatives Use :  
Frequency Report and Registration,  
*Cosmetics & Toiletries*, **121**(7), 65-69 (2006)

# PARABENS'

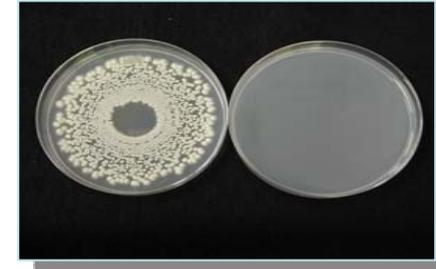
## MICROBACTERIAL EFFECTS



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



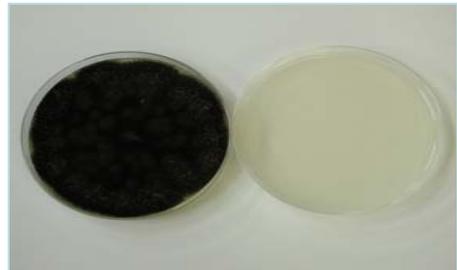
*Staphylococcus aureus*  
IFO 13276 :  
METHYL+PROPYL PARABEN  
(2:1) 0.1%



*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 <sub>50</sub> )	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

# *Paraben in natural products !*

**Paraben is well known to exist in natural products.** Also, we have been using Paraben all over the world for preservative of cosmetics, foods and pharmaceutical additives for a long time, taking advantage of its characteristic.

The chemical name of paraben is "***p*-hydroxybenzoic acid ester**".

Paraben is made by a chemical synthesis, however, it has its advantages for safety, efficiency and cost performance. Due to these reasons, this product can be used widely for many products. Once paraben is absorbed in a body, it disintegrates easily and changes into "***p*-hydroxybenzoic acid**" which is a metabolite of paraben, and will be excreted immediately <sup>1)</sup>.

**As for the paraben or *p*-hydroxybenzoic acid are classified as polyphenol in plants. In addition, it has been well known that they are included in many vegetables and fruits (typical of berries) <sup>2-5)</sup> for a long time.**



# *Paraben in natural products !*

**In recent years, antibacterial and/or antioxidative effect in vegetable or plant oil (ex. carrot, tomato, rapeseed oil, olive oil) receives great attention, and these products are known to include paraben and *p*-hydroxybenzoic acid<sup>6-9</sup>.**

As we have explained, there are many reports of the paraben or *p*-hydroxybenzoic acid in plants. In our everyday life, we have many opportunities to touch or to eat parabens, and we have used antibacterial or preservative effects of paraben since early times.

**Paraben is a good example that we manufacture certain products in natural products through chemical synthesis, and apply this product in human life.**



## References

- 1 Soni, M.G. Food and Chemical Toxicology. 2005, 43: 985-1015.
- 2 Tomaszewski, M. Bull. Acad. Polonaise Sci. 1960, 8: 61-65.
- 3 Schmidlein, H. J Chromatogy. 1975, 115: 123-128.
- 4 Baardseth, P. Food Chemistry. 1978, 3 (1): 43-46.
- 5 Schäfers, F. I. Journal of Chromatography, 1982, 240 (2); 21: 387-396.
- 6 Mandal, S. Physiological and Molecular Plant Pathology. 2007, 1 (4-6): 201-209.
- 7 Kang Y. H. J Agric Food Chem. 2008, Sep.24; 56(18): 8558-64.
- 8 Siger, A. Journal of Food Lipids 2008, 15: 137-149.
- 9 Salta, F. N. Food Sci Tech Int. 2007, 13 (6): 413-421.

# 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.