



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## **Product Safety Assessment**

Pink Gin Fizz

Darllly Europe Limited

**Reference** F4S007

**Issue** 1

**Issue Date** 29-Jun-20

### **Pink Gin Fizz**

Sponsor Darllly Europe Limited  
Unit 18 Cedar Court  
Halesfield 17  
Telford  
Shropshire

### ***Part A***

#### **Section 1 - Quantitative and Qualitative Composition**

<b>Ingredient</b>	<b>CAS Number</b>	<b>%w/w</b>
Sodium Chloride	7647-14-5	98.995
Parfum	n/a	1.005
Limonene	5989-27-5	0.001
Linalool	78-70-6	0.000
Citronellol	106-22-9, 26489-010-0	0.000
Geraniol	106-24-1	0.000
Methyl 2-Octynoate	111-12-6	0.000
Butylphenyl methylpropional	80-54-6	0.000
Citral	5392-40-5	0.000
CI 15985	2783-94-0	0.000
Coumarin	91-64-5	0.000



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

**Product Safety Assessment**

Pink Gin Fizz

Darby Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

Quantities below third decimal place not reported on this table, but have been used in calculations later in the report.



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## **Product Safety Assessment**

Pink Gin Fizz

Darby Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

## **Section 2 - Product Characteristics**

### **Ingredient List**

Sodium Chloride, Parfum, CI 15985

**Adult or Child**

Adult



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## **Product Safety Assessment**

Pink Gin Fizz

Darby Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

### **Section 3 - Microbiological Quality**

The preservative efficacy of this product is likely to be confirmed if challenged by a standard efficacy test given that the levels of preservative are at a level generally found to be of an appropriate microbiological standard.

### **Section 4 - Impurities and packaging**

This formulation does not contain any ingredients with toxicologically relevant impurities.

There are no known or likely interactions with the pack that have any safety implications.

### **Section 5 - Normal and Foreseeable Use**

This product is intended for topical application to a limited body area in small quantities.

### **Section 6 - Exposure**

**Where Used** This product is applied to the skin

**Estimated Daily Amount Used** 30 g

**Frequency Of Use** Daily

**Assumed Body Weight** 60 Kg

**Rinse Status** Leave On

### **Section 7 - Exposure to Ingredients**

<b>Ingredient</b>	<b>CAS Number</b>	<b>%w/w</b>	<b>Dose</b>	<b>SED</b>	<b>NOAEL</b>	<b>MoS</b>
Sodium Chloride	7647-14-5	98.995	0.000	4.975		
Parfum	n/a	1.005	0.000	5.025		

**Product Safety Assessment**

Pink Gin Fizz

Darley Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

Limonene	5989-27-5	0.001	0.000	0.004	250	58736.7
Linalool	78-70-6	0.000	0.000	0.002	500	320967
Citronellol	106-22-9, 26489-010-0	0.000	0.000	0.000	50	442222
Geraniol	106-24-1	0.000	0.000	0.001	1000	1895240
Methyl 2-Octynoate	111-12-6	0.000	0.000	0.001		
Butylphenyl methylpropional	80-54-6	0.000	0.000	0.000	4125	2.7E+07
Citral	5392-40-5	0.000	0.000	0.000	1400	1.2E+07
CI 15985	2783-94-0	0.000	0.000	0.000		
Coumarin	91-64-5	0.000	0.000	0.000		

The Margin of Safety (MoS) is calculated by working out the maximum feasible exposure and comparing it to the level at which no adverse effect is observed ( the NOAEL). If the MoS is 100 then the use level is one hundredth the level at which any effect is observed. Any level above 100 is considered to be acceptable.



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## Product Safety Assessment

Pink Gin Fizz

Darfly Europe Limited

Reference F4S007

Issue 1

Issue Date 29-Jun-20

## Section 8 - Toxicological Profile of Ingredients

### ***Butylphenyl Methylpropional***

80-54-6

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

Due to its sensitisation potential the IFRA standards limit its use in this category of product, but the limit is many orders of magnitude greater than it is used in this product so this raises no issues.

The NOAEL used is not strictly speaking appropriate to assess the risk of systemic absorption, given that it is from a study into sensitisation. However it is highly unlikely to have a lower value for systemic toxicity giving no reason to doubt its safety at the use level in this product.

IFRA standards 43rd Amendment 2009.



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

**Product Safety Assessment**

Pink Gin Fizz

Darfly Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

**CI 15985**

2783-94-0

CI 15985 is still sometimes referred to by its old FDA name of FD&C Yellow No. 6, even though the current name is Yellow 6. CI 15985 is permitted at any level under the EU cosmetic regulations subject only to the proviso that the purity criteria as set out in Commission Directive 95/45/EC (E 110) are met - a condition that the grade used in this product meets.

It appears on the FDA's Food Additive Status List on List 1, permitted for use in food, cosmetics and pharmaceuticals.

BIBRA's Working Group found no evidence of toxic effects from this material. A long term study in mice revealed no toxic effects.

There is no suitable NOAEL available for this material in the literature, but given its widespread use as a food colouring (EFSA estimates consumption in children in UK could be as high as 1.19mg/Kg bw per day) a margin of safety calculation for small amount applied to the skin is not necessary.

EU Cosmetic Regulations EU1223/2009

FDA Food Additive Status List

BIBRA Working Group 1995 Sunset Yellow

Food Cosmet Toxicol; 12 (1). 1974 1-10 Long-term toxicity of Sunset Yellow FCF in mice Gaunt IF, Mason PL, Grasso P, Kiss IS

EFSA Journal 2011;9(9):2349 Revised exposure assessment for Sunset Yellow FCF based on the proposed revised maximum permitted levels of use as a food additive



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## Product Safety Assessment

Pink Gin Fizz

Darley Europe Limited

Reference F4S007

Issue 1

Issue Date 29-Jun-20

### **Citral**

5392-40-5

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

Citral is a naturally occurring material that is a common part of the regular diet. It does however have the potential to be a sensitiser and to provoke allergic reactions. Allergic reactions are impossible to avoid completely, but research has been carried out to assess if there is a level below which dermal sensitisation can be eliminated. Research is still limited in this area and it is likely that formulation factors as yet unstudied will strongly affect the sensitisation process. The figure used for the NOAEL calculation is derived from work in this area and shows that at the level in this formulation a sensitisation reaction is very unlikely indeed.

The IFRA standards booklet lists this material as restricted, with the following limits on particular categories -.

Lip Products -0.04%  
Deodorants/Antiperspirants 0.05%  
Hydroalcohols for Shaved Skin 0.2%  
Hydroalcohols for Unshaved Skin 0.6%  
Hand Cream 0.3%  
Mouthwash 1%  
Intimate Wipes 0.1%  
Hair Styling Aids 1.4%  
Rinse-off Hair Conditioners 5%

The level in this product is compliant with these guidelines.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipesi, H. Tagami

Regul Toxicol Pharmacol. 2008 Oct;52(1):62-73. doi: 10.1016/j.yrtph.2008.01.006. Epub 2008 Jan 26. Citral: identifying a threshold for induction of dermal sensitization. Lalko J, Api AM.

IFRA Standards Booklet 47th Amendment 2013



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## Product Safety Assessment

Pink Gin Fizz

Darley Europe Limited

Reference F4S007

Issue 1

Issue Date 29-Jun-20

### ***Citronellol***

106-22-9, 26489-010-0

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The IFRA guidelines limit citronellol to below 1.1%, a limit this product complies with.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipesi, H. Tagami

### ***Coumarin***

91-64-5

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

It is a food ingredient which has a low level of toxicity. Unusually, an LD50 has been calculated for this material in female humans. This was based on work in patients with liver malfunctions treated with coumarin, and so may not be directly applicable to a healthy population, but even so indicates a very low level of toxicity.

Given its widespread consumption in food, there is no need for a margin of safety calculation to conclude that this material can be safely applied in small quantities to the skin as in this product.

Molecular Nutrition & Food Research Toxicology and risk assessment of coumarin: Focus on human data Klaus Abraham, Friederike Wöhrin, Oliver Lindtner, Gerhard Heinemeyer and Alfonso Lampen

Hum Toxicol. 1989 Nov;8(6):501-6. The rarity of liver toxicity in patients treated with coumarin (1,2-benzopyrone). Cox D1, O'Kennedy R, Thorne RD.



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

**Product Safety Assessment**

Pink Gin Fizz

Darby Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

***Geraniol***

106-24-1

Geraniol is pale-yellow oil with a rose odour.

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

The use level is well within the IFRA guideline for this material in this class of product, IFRA's main concern being to limit the risk of sensitisation.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## Product Safety Assessment

Pink Gin Fizz

Darley Europe Limited

Reference F4S007

Issue 1

Issue Date 29-Jun-20

### ***Limonene***

5989-27-5

Limonene is a terpene that is found in citrus fruits and consequently is commonly ingested. As such it is listed by the FDA as generally recognised as safe (GRAS). Given this, a NOAEL is not particularly relevant to the assessment of its safety. A review of flavouring ingredients by EFSA confirmed this assumption. Even so a value has been assigned to it and when an MoS is calculated it is acceptable.

This material is not often used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products. Its concentration in this product conforms to IFRA guidelines.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) . Scientific Opinion on Flavouring Group Evaluation 25, Revision 2 (FGE.25Rev2): Aliphatic and aromatic hydrocarbons from chemical group 31 . EFSA Journal 2011; 9(6):2177. [126 pp.]. doi:10.2903/j.efsa.2011.2177. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

J Toxicol Environ Health B Crit Rev. 2013;16(1):17-38. doi: 10.1080/10937404.2013.769418.  
Safety evaluation and risk assessment of d-Limonene. Kim YW, Kim MJ, Chung BY, Bang du Y, Lim SK, Choi SM, Lim DS, Cho MC, Yoon K, Kim HS, Kim KB, Kim YS, Kwack SJ, Lee BM.

IFRA Standards 20

### ***Linalool***

78-70-6

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

Int J Toxicol. 2008 Mar-Apr;27(2):183-8 Evaluation of the developmental toxicity of linalool in rats. Politano VT, Lewis EM, Hoberman AM, Christian MS, Diener RM, Api AM.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipesi, H. Tagami



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## Product Safety Assessment

Pink Gin Fizz

Darby Europe Limited

Reference F4S007

Issue 1

Issue Date 29-Jun-20

### ***Methyl 2-octynoate***

111-12-6

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

### ***Parfum***

n/a

The fragrance blend has been formulated in compliance with IFRA guidelines for this product to ensure that its safety is satisfactory. Components do not need to be listed, except for those designated as allergens under EU cosmetic legislation which are present at the level above the cut off point in the legislation.

EU Cosmetic Regulations EU1223/2009

### ***Sodium Chloride***

7647-14-5

Sodium Chloride, or table salt, is a white crystalline solid and is one of the most familiar ingredients in food with a track record that predates recorded history. In cosmetics and personal care products, Sodium Chloride is used in the formulation of oral hygiene products, shampoos, fragrance, skin, hair, nail, cleansing, suntan, makeup and bath products.

The Food and Drug Administration (FDA) reviewed the safety of Sodium Chloride and approved its use as an active ingredient in Over-The-Counter (OTC) drug products for the eyes at concentrations of 2 to 5%.

In addition to being an important component of food, FDA includes Sodium Chloride on its list of substances considered Generally Recognized as Safe (GRAS) as a substance migrating to food from packaging.

The Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has been assessed by FDA. Sodium chloride is a foodstuff and a regular component of the body'. There are issues with prolonged consumption but the tiny contribution made to the diet by any sodium chloride absorbed from cosmetic products is obviously trivial and no margin of safety calculation is appropriate.

Select Committee on GRAS Substances (SCOGS) Opinion: Sodium Chloride Report 102 21 CFR Section: 182.70

## **Section 9 - Undesirable Effects**



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

**Product Safety Assessment**

Pink Gin Fizz

Darby Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

No undesirable effects are foreseen with this product when used under conditions of normal and foreseeable use.



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## **Product Safety Assessment**

Pink Gin Fizz

Darfly Europe Limited

**Reference** F4S007  
**Issue** 1  
**Issue Date** 29-Jun-20

### ***Part B***

#### **Section 1- Assessment Conclusion**

This product has been assessed and found to comply with the requirements of current EU and US cosmetic regulations. The ingredients selected have been reviewed and are used at levels suitable to ensure that the end user will experience the level of safety they can reasonably expect for this kind of product when used in accordance with the manufacturers instructions, and when manufactured following a suitable cosmetic GMP procedure.

#### **Section 2- Labels and Warnings**

This product does not require any specific warnings over and above those customary for this category of product.

#### **Section 3- Reasoning**

This is a standard product using conventional ingredients at normal levels. This category of products has a good track record of safe use and so can be presumed to be safe under normal and foreseeable conditions of use. Interactions between ingredients are unlikely to be problematic in this kind of product.



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

**Product Safety Assessment**

Pink Gin Fizz

Darby Europe Limited

**Reference** F4S007

**Issue** 1

**Issue Date** 29-Jun-20

**Signed**

Colin Sanders

A handwritten signature in black ink that reads "Colin Sanders".

08/09/2020



Colin's Cosmetic Consultancy Ltd  
5 Lombard Street  
Petworth  
West Sussex  
GU28 0AG

## **Product Safety Assessment**

Pink Gin Fizz

Darilly Europe Limited

**Reference** F4S007

**Issue** 1

**Issue Date** 29-Jun-20

## **Appendix - Credentials of Assessor**

Colin Sanders Bsc(Hons) FRSB Dip SCS  
Date of Birth 19.5.1960

### Academic Qualifications

Bachelor of Science in Environmental Science from Leicester Polytechnic, lower second with honours awarded in 1983.

Diploma in Cosmetic Science awarded by the Society of Cosmetic Science awarded in 1985

### Membership of Professional Bodies

Society of Cosmetic Scientists

Fellow of the Royal Society of Biology

### Experience

Development Chemist at Intergen Cosmetics 1983-1987

Quality Assurance W.M.Stills 1987-1990

Formulation Scientist/Formulation Laboratory Manager Stiefel Laboratories 1990-2004

Head of Product Formulation Medex/Montagne Jeunesse 2004-2013