

PREMIUM FACTORY

Professional :: Special Effects



Product Information File

Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/ Purple

This file serves to comply with Regulation (EC) No 1223/2009

Initial date	07-04-2016
Issued	08-04-2016

This dossier is strictly confidential. No part of it may be reproduced in any form without written permission of Kingdom of Colors BV, Mastwijkerdijk 108E, 3417 BT Montfoort, Nederland

Product information file



This file serves to comply with Regulation (EC) No 1223/2009.

CONTENT

1. Product description
2. Cosmetic Product Safety Report
3. Method of manufacture and statement of GMP compliance
4. Proof of effect for the product
5. Data on animal testing

This file is strictly confidential. No part of it may be reproduced in any form without written permission of Kingdom of Colors BV, Mastwijkerdijk 108E, 3417 BT Montfoort, Nederland

1. Product description



PRODUCT INFORMATION

Product name	: Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Product code	: KOC-002
Product category	: Powder products
Product type	: Colour powders (fun article)
Formula name	: Holi Color Powder coloured
Formula code	: KOC-002
CPNP reference	: 2133040

MANUFACTURER

PACKAGING OF THE PRODUCT

FILE COORDINATOR

Company name	: INFO CARE B.V.
Address	: Tiberiusweg 9
Place	: DE MEERN
Telephone	: +31 30 6620235
Company representative	: Ing. J.M. van de Hoef - van Veldhuizen
Qualifications	: Senior Cosmetic Safety Officer

RESPONSIBLE NATURAL PERSON

Company name	: Kingdom of Colors BV
Address	: Mastwijkdijk 108E
Place/Country	: Montfoort
Telephone	: +31-6 248 14331

CONTENT OF CPSR

Part A Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product
2. Physical/chemical characteristics and stability of the cosmetic product
3. Microbiological quality
4. Impurities, traces, information about the packaging material
5. Normal and reasonably foreseeable use
6. Exposure to the cosmetic product
7. Exposure to the substances
8. Toxicological profile of the substances
9. Undesirable effects and serious undesirable effects
10. Information on the cosmetic product

Part B Cosmetic product safety assessment

1. Assessment conclusion
2. Labelled warnings and instructions of use
3. Reasoning
4. Assessor's credentials and approval of part B

1. Quantitative and qualitative composition



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. COMPOSITION OF THE FORMULA

Trade name	%	Manufacturer/supplier
Sodium bicarbonate (TATA)	1.690000	Tata Chemicals Europe
FD&C Red No. 3	2.000000	Dynemic Products Ltd
FD & C Blue 1	2.000000	Dynemic Products Ltd
FD & C Yellow #6	2.000000	Dynemic Products Ltd
Maize Starch Powder	60.080000	Roquette Riddhi Siddhi Pvt, Ltd.
Tri Calcium Phosphate	18.780000	Shiva Inorganics
Sodium Chloride IP	11.260000	Loba Chemie PVT.Ltd.
Methyl paraben (Cosmos)	0.190000	Cosmos Plastics & Chemicals
FD & C Yellow #5	2.000000	Dynemic Products Ltd

3. INFORMATION FOR PUBLIC ACCESS

Information in accordance with Regulation (EC) No. 1223/2009, article 21.

INCI name	%
ZEA MAYS STARCH	
TRICALCIUM PHOSPHATE	
SODIUM CHLORIDE	
CI 45430	1 - 5
CI 42090	
CI 19140	
CI 15985	
SODIUM BICARBONATE	
SODIUM FERROCYANIDE	
METHYLPARABEN	0,01 - 1

1. Quantitative and qualitative composition



Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

4. FORMULA BREAKDOWN

RM trade name	INCI name	CAS number	EC number	Composition function	Cosmetic function
Maize Starch Powder	ZEAMAYSTARCH	9005-25-8	232-679-6	Ingredient	abrasive / absorbent / anticaking/ skin protecting / viscosity controlling
Tri Calcium Phosphate	TRICALCIUM PHOSPHATE	7758-87-4	231-840-8	Ingredient	abrasive / anticaking / masking / opacifying / oral care
Sodium Chloride IP	SODIUM CHLORIDE	7647-14-5	231-598-3	Ingredient	bulking / masking / oral care / viscosity controlling
Sodium Chloride IP	SODIUM FERROCYANIDE	13601-19-9	237-081-9	Additive	anticaking
FD&C Red No. 3	CI 45430; ACID RED 51	16423-68-0	240-474-8	Ingredient	cosmetic colorant
FD&C Red No. 3	SODIUM CHLORIDE	7647-14-5	231-598-3	Contaminant	
FD&C Red No. 3	SODIUM SULFATE	7757-82-6	231-820-9	Contaminant	
FD & C Blue 1	CI 42090; ACID BLUE 9	3844-45-9	223-339-8	Ingredient	cosmetic colourant / hair dyeing
FD & C Blue 1	SODIUM CHLORIDE	7647-14-5	231-598-3	Contaminant	
FD & C Blue 1	SODIUM SULFATE	7757-82-6	231-820-9	Contaminant	
FD & C Yellow #6	CI 15985	2783-94-0	220-491-7	Ingredient	cosmetic colorant
FD & C Yellow #6	SODIUM CHLORIDE	7647-14-5	231-598-3	Contaminant	
FD & C Yellow #6	SODIUM SULFATE	7757-82-6	231-820-9	Contaminant	
FD & C Yellow #5	CI 19140; ACID YELLOW 23	1934-21-0	217-699-5	Ingredient	cosmetic colorant / hair dyeing
FD & C Yellow #5	SODIUM CHLORIDE	7647-14-5	231-598-3	Contaminant	
Sodium bicarbonate (TATA)	SODIUM BICARBONATE	144-55-8	205-633-8	Ingredient	abrasive / buffering / deodorant / oral care / skin protecting
Methyl paraben (Cosmos)	METHYL PARABEN	99-76-3	202-785-7	Ingredient	preservative

2. Physical / Chemical Characteristics And Stability



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. FORMULA SPECIFICATIONS

Color	: Red/Green/Blue/Orange/Pink/Yellow/Purple
Appearance	: Solid
Odour	: Characteristic
pH	: NA
Viscosity (20° C)	: NA
Density	: Not known
Remarks	:

3. PRODUCT SPECIFICATIONS

Appearance	: Labeled, clean, non damaged.
Artwork	:
Contents	: 70/100 g
Remarks	:

4. RESULTS STABILITY TESTING

Performing laboratory :

After storage for 13 weeks at room temperature and at 40 °C the product has been tested on:

- the parameters mentioned in chapter 3 under formula specifications;
- interaction between formula and packaging;
- stability of the packaging.

Results are filed in the test reports mentioned below. No unacceptable changes in appearance, stability and performance are observed.

Based on generally accepted principles of accelerated storage stability testing and to the best of our knowledge and experience the product is believed to be stable for at least 30 months.

5. TEST REPORTS

No test report available.

Based on experience for many years, the product will be stable at room temperature for at least 36 months. There are no significant changes observed in appearance, colour and odour.

3. Microbiological Quality



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. CHALLENGE TESTS / TEST REPORTS

Performing laboratory :
Challenge test :
Remark :

3. MICROBIOLOGICAL QUALITY *

Performing laboratory :
Cosmetic category : Category 2: Other products, not specifically intended for children under 3 years, to be used in the eye area and on mucous membranes.
Quantitative microbiological limits : Total Viable Count (TVC) < 1000 cfu/g or 1000 cfu/ml of the product
Qualitative microbiological limits: Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans not detectable in 0,1 g or 0,1 ml of the product.
Microbiological control on production sample :
Remark : Based on experience with the product for many years and the fact that the product is a powder, no microbiological growth is expected for this product. A microbiological quality test will be performed to support the quality of the product after production. This report will be added as soon as available.
*reference : Reference : adopted by the SCCP 23 September 1998.

4. Impurities, Traces and Packaging Material



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. PURITY OF THE SUBSTANCES AND MIXTURES

See Part A - 1. Quantitative and qualitative composition

3. TRACES OF PROHIBITED SUBSTANCES

Prohibited substances: ---

4. PACKAGING DOCUMENTATION

5. REMARKS

At the time of compiling this product file, the packaging information and the documentation as enclosed was believed to be up-to-date and the best possible information that could be obtained, directly or indirectly, from suppliers.

5. Normal And Foreseeable Use



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. NORMAL AND REASONABLE FORESEEABLE USE

Normal use	: Powder products Colour powders fun article
Application	: Topical
Foreseeable use	:

3. ASSESSMENT FOR PACKAGING AND INSTRUCTIONS FOR USE

User group	: Adults and children
Packaging	: Pouch
Volume	: 70 /100 g
Instructions for use	: ---
Mandatory warnings	: ---
Recommended warnings	: ---
Assessment	: The packaging provides no reason for special hazards or deviating use.

6. Exposure to Cosmetic Product



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. EXPOSURE TO THE PRODUCT

Product type : Leave-on
Area of application : skin/hair
Usage quantity of product : 8.0000 gram per application
Usage frequency : 0.01 time(s) per day
Retention factor : 1.00
Exposed skin surface : 15670.00 cm²
Body weight : 60.00 kg
Exposure duration : hours
Percutaneous absorption : No data available for the cosmetic product
Foreseeable exposure routes : dermal/oral/inhalation
User group : Adults and children

3. REMARKS

Particle size : mean particle size 90 µm.

7. Exposure to the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. EXPOSURE TO THE SUBSTANCES

INCI name	Dermal absorption(%)	Log P(o/w)	Mol weight	SED (dermal) acute (mg/kg.bw/day)	SED (dermal) chronic (mg/kg.bw/day)
ZEA MAYS STARCH	100			78.865013	0.788650
TRICALCIUM PHOSPHATE	100	-----	310,2	24.827160	0.248272
SODIUM CHLORIDE	100	-3,0	58,5	15.376523	0.153765
CI 45430; ACID RED 51	100	-0,29	879,9	2.493333	0.024933
CI 42090; ACID BLUE 9	0.6	-4,0000	792,8	0.014800	0.000148
CI 19140; ACID YELLOW 23	100	-10,17	534,36	2.466667	0.024667
CI 15985	1	-0,244	454,40	0.024667	0.000247
SODIUM BICARBONATE	100		84,02	2.253333	0.022533
METHYLPARABEN	84.7	1,98	152,16	0.214573	0.002146
SODIUM SULFATE	100	-3	142,04	0.007467	0.000075
SODIUM FERROCYANIDE	100	-0,25	303,91	0.000015	0.000000

Note: The listed SED is calculated with the absorption factor for oral exposure. When dermal exposure is used the absorption factor should be 100.

Absorption factor used for SED calculation:

Dermal absorption	x%
Log Po/w > 6	1%
Polymer or MW > 5000	1%
MW > 1500	10%
MW > 500 and Log Po/w < -1 or > 4	10%

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. ACUTE TOXICITY

INCI name	Dermal toxicity LD50 (mg/kg)	Species	Method	Oral toxicity LD50 (mg/kg)	Species	Method
ZEA MAYS STARCH	-----			-----		
TRICALCIUM PHOSPHATE	> 7940	Rabbit	Read across	> 5000	Rat	
SODIUM CHLORIDE	> 10000	Rabbit	-----	3000	Rat	-----
CI 45430; ACID RED 51	-----			1840	Rat	
CI 42090; ACID BLUE 9	-----			> 5000	Rat	-----
CI 19140; ACID YELLOW 23	-----			> 12000	Mouse	-----
CI 15985	-----			> 2000	Rat	
SODIUM BICARBONATE	-----			4220	Rat	-----
METHYLPARABEN	-----			2100	Rat	OECD 401
SODIUM SULFATE	-----			> 2000	Rat	OECD 423
SODIUM FERROCYANIDE	> 2000	Rat	OECD 402	> 5110	Rat	OECD 401

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. PRIMARY IRRITATION

INCI name	Skin Irritation	Species	Method	Eye Irritation	Species	Method
ZEA MAYS STARCH	-----			-----		
TRICALCIUM PHOSPHATE	Non-irritant			Mildly irritant	Rabbit	
SODIUM CHLORIDE	Slightly irritant	-----	-----	Irritant	-----	-----
CI 45430; ACID RED 51	Slightly irritant	Rabbit		Mildly irritant	Rabbit	
CI 42090; ACID BLUE 9	Non-irritant	Rabbit	OECD 404	Non-irritant	Rabbit	OECD 405
CI 19140; ACID YELLOW 23	Non-irritant	Rabbit	-----	Non-irritant	Rabbit	-----
CI 15985	Non-irritant	Rabbit		Minimally irritant	Rabbit	
SODIUM BICARBONATE	Mildly irritant	Rabbit	OECD 404	Mildly irritant	Rabbit	
METHYLPARABEN	Slightly irritant		-----	Slightly irritant	Rabbit	-----
SODIUM SULFATE	Non-irritant	Rabbit	OECD 404	Slightly irritant	Rabbit	OECD 405
SODIUM FERROCYANIDE	Non-irritant	Rabbit	OECD 404	Non-irritant	Rabbit	OECD 405

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. SENSITIZATION

INCI name	Sensitization (ug/cm2)	Species	Method	Sensitization EC3 (%)	Species	Method
ZEA MAYS STARCH	Not sensitizing	Guinea pig	Read across	----		
TRICALCIUM PHOSPHATE	Not sensitizing	Mouse	Read across	----		
SODIUM CHLORIDE	Not sensitizing	Mouse	----	----		
CI 45430; ACID RED 51	Not sensitizing		Read across			
CI 42090; ACID BLUE 9	Not sensitizing	Human	Patch test	100	Mouse	OECD 429
CI 19140; ACID YELLOW 23	Not sensitizing	Guinea pig	OECD 406	----		
CI 15985	Not sensitizing	Guinea pig	Read across	----		
SODIUM BICARBONATE	Not sensitizing			----		
METHYLPARABEN	Not sensitizing	Guinea pig	Maurer optimization test	----		
SODIUM SULFATE	Not sensitizing	Guinea pig	OECD 406	----		
SODIUM FERROCYANIDE	Not sensitizing	Guinea pig	OECD 406	Not sensitizing	Mouse	OECD 429

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. CHRONIC TOXICITY

INCI name	(Sub)Chronic dermal toxicity	Species	Method	Test Duration	(Sub)Chronic oral toxicity	Species	Method	Test Duration
ZEA MAYS STARCH	-----				-----			
TRICALCIUM PHOSPHATE	-----				1000	Rat	OECD 422	28 d
SODIUM CHLORIDE	-----				1330	Rat		90 d
CI 45430; ACID RED 51	-----				> 60			
CI 42090; ACID BLUE 9	-----				> 631	Rat		2 yr
CI 19140; ACID YELLOW 23	-----				8103	Mouse		2 yr
CI 15985	-----				16000	Mouse		1 yr
SODIUM BICARBONATE	-----				-----			
METHYLPARABEN	-----				> 250	Rat	OECD 407	
SODIUM SULFATE	-----				2000	Rat	-----	28 d
SODIUM FERROCYANIDE	-----				450	Rat	OECD 453	2 yr

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. CHRONIC TOXICITY - CARCINOGENICITY

INCI name	Carcinogenicity (mg/kg.bw/d)	Species	Method	Carcinogenicity(Oral) (mg/kg.bw/d)	Species	Method
ZEA MAYS STARCH	----			----		
TRICALCIUM PHOSPHATE	----			----		
SODIUM CHLORIDE	----			Not carcinogenic	Rat	OECD 453
CI 45430; ACID RED 51	Not carcinogenic	Mouse		Not carcinogenic	Rat	
CI 42090; ACID BLUE 9	----			Not carcinogenic	Rat	
CI 19140; ACID YELLOW 23	----			2641	Rat	
CI 15985	----			----		
SODIUM BICARBONATE	----			Not carcinogenic	Rat	
METHYLPARABEN	Not carcinogenic	Rat		Not carcinogenic	Rat	
SODIUM SULFATE	----			> 400	Rat	
SODIUM FERROCYANIDE	----			----		----

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. CHRONIC TOXICITY - MUTAGENICITY

INCI name	Mutagenicity	Species	Method
ZEA MAYS STARCH	-----		
TRICALCIUM PHOSPHATE	Not mutagenic	Salmonella typhimurium	OECD 471
SODIUM CHLORIDE	Negative		OECD 471
CI 45430; ACID RED 51	Negative	Salmonella typhimurium	OECD 471
CI 42090; ACID BLUE 9	Negative	Salmonella typhimurium	OECD 471
CI 19140; ACID YELLOW 23	Negative	Salmonella typhimurium	OECD 471
CI 15985	Negative	Salmonella typhimurium	OECD 471
SODIUM BICARBONATE	Negative	Salmonella typhimurium	
METHYLPARABEN	Negative	Salmonella typhimurium	OECD 471
SODIUM SULFATE	Negative	Salmonella typhimurium	OECD 471
SODIUM FERROCYANIDE	Negative		OECD 471

8. Toxicological profile of the substances



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. CHRONIC TOXICITY - REPROTOXICITY

INCI name	Reprotoxicity - fertility (mg/kg.bw/d)	Species	Method	Reprotoxicity - development (mg/kg.bw/d)	Species	Method
ZEA MAYS STARCH	----			----		
TRICALCIUM PHOSPHATE	1000	Rat	OECD 422	----		
SODIUM CHLORIDE	----			----		
CI 45430; ACID RED 51	> 800	Rat		----		
CI 42090; ACID BLUE 9	> 1000	Rat		----		
CI 19140; ACID YELLOW 23	Not reprotoxic	Rat		----		
CI 15985	500	Rat		----		
SODIUM BICARBONATE	----			----		
METHYLPARABEN	----			----		
SODIUM SULFATE	> 1000	Rat	OECD 421	----		
SODIUM FERROCYANIDE	----			----		

9. Undesirable health effects



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. HEALTH RELATED COMPLAINTS

Total complaints (%)	: 0
Health related	: 0% of marketed value
Complaints / incidents	: None with medical follow up None medically acknowledged as product / use related

10. Information on the cosmetic product



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. OTHER INFORMATION

Empty box for other information.

1. Assessment conclusion



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. GUIDELINESS OF SAFETY ASSESSMENT

This safety assessment is executed in conformity with the criteria as stipulated in article 10 of Regulation (EC) No 1223/2009 and SCCP guidelines for the safety assessment of cosmetic ingredients and/or products.

3. DESCRIPTION OF THE PRODUCT AND ITS APPLICATION

Product type : Cosmetics
Application : Topical
Usage quantity of product : 8.0000 gram per application
Usage frequency : 0.01 time(s) per day
Instructions for use :
Mandatory warnings : ---
Recommended warnings : ---

4. COMPOSITION/INFORMATION OF THE COMPONENTS

In general : The product does not contain substances not permitted as meant in Regulation EC No. 1907/2006 Annex XVII (CMR Cat. 1) or Regulation (EC) 1223/2009 Annex II

5. TESTS SUPPORTING THE SAFETY ASSESSMENT

Toxicological animal testing : Neither the finished product, nor its prototypes have been tested on animals. See also Annex IV.
Toxicological tests using alternative methods : Not applicable.

6. INFORMATION

Ingredients	: Supplier material safety data sheets, toxicological profiles and technical information sheets of the components used. Public sources.
Directives	: EC and National regulations on cosmetic products in particular Regulation (EC) No 1223/2009.
Other	: Recommendations from Colipa, SCCP, CIR and other public sources.

7. ASSESSMENT

Having regard to the physical, chemical and toxicological properties of the ingredients.
Having regard to the purpose, intended application and advised use.
Having regard to the expected exposure under normal and reasonable foreseeable conditions of use.
Having regard to the physical and chemical properties of the product.

Provided the formula and finished product are produced according to Cosmetic GMP standards, stable, properly preserved and not contaminated:

It is concluded that 'Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple', given the present level of knowledge and our company's expert review, is unlikely to cause negative health effects to human under normal or reasonable foreseeable conditions of use.

Safety assessor : Ing. J.M. van de Hoef - van Veldhuizen

Date : 08 April 2016

Signature :



Safety assessor : Drs. J.C.J. van Wegen

Date : 08 April 2016

Signature :



8. REMARKS

Disclaimer	: The statement is preliminary. In any case of significant adverse health effects on users during use, a renewed safety assessment should take place.
Additional comments	: Each and every change to the formula and/or its ingredients terminates the validity of this safety assessment.
Extra information	: For supervising authorities detailed information is available at INFO CARE BV, Tiberiusweg 9, 3453 KZ De Meern, Nederland or at PIF owner Kingdom of Colors BV, Mastwijkerdijk 108E, 3417 BT Montfoort, Nederland

2. Label information



1. IDENTIFICATION OF THE PRODUCT


Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. LABEL

On the basis of article 19 of Regulation (EC) No. 1223/2009 the label shall carry the following elements:

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Company name : Kingdom of Colors BV
Address : Mastwijkerdijk 108E
Place/Country : Montfoort
Telephone : +31-6 248 14331
Country of origin : India
Product use : Colour powders (fun article)

Contents : g
Weight (g) : 100

Batch code : Mandatory
Date of minimum durability :  36 M

Ingredient declaration : See `INCI declaration`
The ingredient declaration is to start with the wording `Ingredients:`. Ingredients present in quantities of more than 1% need to be mentioned in descending order. Ingredients present in concentrations of less than 1% can be mentioned in random order

Required storage : Not applicable

3. INCI DECLARATION

ZEA MAYS STARCH
TRICALCIUM PHOSPHATE
SODIUM CHLORIDE
CI 45430
CI 42090
CI 19140
CI 15985
SODIUM BICARBONATE
SODIUM FERROCYANIDE
METHYLPARABEN

4. ARTWORK AND PRODUCT PHOTO

Artwork

Product photo

5. MISCELLANEOUS LABEL ELEMENTS

For products sold in Germany
and/or Austria :



minimum dimensions
6x6 mm

For products sold in France
and/or Belgium :



minimum dimensions
6x6 mm

3. Reasoning



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. PRINCIPLES OF SAFETY ASSESSMENT

The following endpoints have been assessed in accordance with the notes of guidance of the SCCS and the requirements laid down in the Cosmetics Regulation: acute and sub-chronic toxicity for the relevant routes of exposure, phototoxicity, teratogenicity, mutagenicity and carcinogenicity, skin and inhalation sensitisation where applicable and skin and eye irritation.

The evaluation is based on normal or reasonably foreseeable conditions of use. Misuse or use other than intended by for example deliberately swallowing or inhaling is not the primary subject to this assessment.

The user group consists of adults and children. Without special health or age characteristics.

3. INITIAL HAZARD ASSESSMENT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002

Initial hazard review : See table 'Initial hazard assessment' for the presence of hazardous substances and restrictions in the Annex of regulation (EC) No 1223/2009.

Assessment : The product does not contain raw materials, which are not permitted in the sense of Regulation (EC) No 1223/2009.
The product does not contain ingredients, which are not permitted in the sense of Regulation (EC) No 1223/2009.

4. ASSESSMENT FOR PACKAGING AND INSTRUCTIONS FOR USE

User group : Adults and children

Packaging : Pouch
Application : Colour powders (fun article)

Instructions for use :
Mandatory warnings : ---

Recommended warnings : ---

Assessment : The packaging provides no reason for special hazards or deviating use.

5. EXPOSURE

Usage quantity of product	: 8.0000	gram per application
Usage frequency	: 0.01	time(s) per day
Retention factor	: 1.00	
Exposed skin surface	: 15670.00	cm ²
Body weight	: 60.00	kg

Systemic exposure dose (SED) : The SED is calculated as follows:

$$\text{SED} = (A \text{ (mg/day)} * C \text{ (\%)} / 100 * \text{DAp (\%)} / 100) / \text{BW (kg)}$$

A = Estimated daily exposure to a cosmetic product

C = Concentration of substance in the product

DAp = Dermal absorption

BW = Body weight

The SED is calculated according to the SCCS's Notes of Guidance, 8th revision, 2012

For specific baby products the body weight is 6,2 kg* otherwise 60 kg is used.

* H.J. Bremmer, L.C.H. Prud'Homme de Lodder, J.G.M. van Engelen, Cosmetics Fact Sheet, RIVM, 2006

6. MARGINS OF SAFETY

Margin of safety calculation : The Margin of Safety (MoS) is calculated as follows:

$$\text{MoS} = \text{NOAEL} / \text{SED}$$

In case of a 28 days NOAEL an extra factor 3 is applied.

Margins of safety : See table 'Toxicological Evaluation - Margins of Safety'.

MoS discussion : Safety motivation(s) for substances for which MoS calculations for one or more toxicological end points are indecisive and for which expert reviews by e.g. SCCS, CIR, EFFA/IFRA miss:

CI 15985

Within limits Annex IV/31, purity conform criteria E 110.

CI 45430; ACID RED 51

Within limits Annex IV/80, purity conform criteria E 127.

CI 19140; ACID YELLOW 23

Within limits Annex IV/44, purity conform criteria E102.

CI 42090; ACID BLUE 9

Within limits Annex IV/63, purity conform criteria E 133.

During use of the colour powder there is a possibility of inhalation. The mean particle size of the powders is about 90 µm, respiration is therefore unlikely. Inhalation may however result in coughing and irritation. Inhalation of the powders results in an exposure not very different from oral exposure. Given the application, the use is incidental with relative concentrated use, acute toxicity is a more realistic safety indicator than repeated exposure. The safety for oral and dermal acute exposure provides no reason for concern.

4. Initial hazard assessment



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code : KOC-002
Issue date : 24-03-2016

2. INITIAL HAZARD ASSESSMENT

INCI name	R-Phrases	Annex EC No. 1223/2009	Limitations in cosmetics	Warning on cosmetics
ZEA MAYS STARCH	----	----		
TRICALCIUM PHOSPHATE	----	----		
SODIUM CHLORIDE	----	----		
CI 45430; ACID RED 51	----	II/1337; IV/80	Not allowed in hairdyes.. Purity criteria as set out in Commission Directive 95/45/EC (E127)	
CI 42090; ACID BLUE 9	----	III/190; IV/63	III: Max. 0,5% as hair dye substance in nonoxidative hair dye products. . IV: Purity criteria as set out in Commission Directive 95/45/EC (E 133)	
CI 19140; ACID YELLOW 23	----	III/189; IV/44	III: max. 0,5% as hair dye substance in nonoxidative hair dye products.. IV: Purity crieteria as set out in Commission Directive 95/45/EC (E102)	
CI 15985	----	IV/31	Purity criteria as set out in Commission Directive 95/45/EC (E 110)	
SODIUM BICARBONATE	----	----		
METHYLPARABEN	----	V/12	Max. 0,4 % (as acid) for single ester, max. 0,8 % (as acid) for mixtures of esters.	
SODIUM SULFATE	----	----		
SODIUM FERROCYANIDE	----	----		

Toxicological evaluation - Margins of Safety



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. MARGINS OF SAFETY

INCI name	Acute dermal toxicity	Acute oral toxicity	(Sub)Chronic dermal toxicity	(Sub)Chronic oral toxicity	Skin sensitisation	Mutagenicity	Genotoxicity (in vivo)	Carcinogenicity (Dermal)	Reprotoxicity (fertility)	Reprotoxicity (development)	Carcinogenicity (Oral)
CI 15985	LD50 missing	811	NOAEL missing	648649	NOEL missing	Negative	NOEL missing	NOEL missing	20270	NOAEL missing	NOEL missing
SODIUM FERROCYANIDE	133214920	340364121	NOAEL missing	2997335702	No evidence	Negative	NOEL missing	NOEL missing	NOAEL missing	6660746004	NOEL missing
METHYLPARABEN	LD50 missing	8289	NOAEL missing	32763	No evidence	Negative	197368	NOEL missing	NOAEL missing	217105	NOEL missing
TRICALCIUM PHOSPHATE	LD50 missing	201	NOAEL missing	1341	NOEL missing	Not mutagenic	NOEL missing	NOEL missing	4028	4028	NOEL missing
SODIUM CHLORIDE	650	195	NOAEL missing	NOAEL missing	NOEL missing	Negative	NOEL missing	NOEL missing	NOAEL missing	NOAEL missing	No evidence
CI 42090; ACID BLUE 9	LD50 missing	2027	NOAEL missing	25581	44115991	Negative	81081	NOEL missing	40541	No evidence	No evidence
CI 45430; ACID RED 51	LD50 missing	738	NOAEL missing	2406	NOEL missing	Negative	NOEL missing	No evidence	32086	NOAEL missing	No evidence
CI 19140; ACID YELLOW 23	LD50 missing	4865	NOAEL missing	328500	No evidence	Negative	No evidence	NOEL missing	No evidence	40541	107068
ZEA MAYS STARCH	LD50 missing	LD50 missing	NOAEL missing	NOAEL missing	No evidence	----	NOEL missing	NOEL missing	NOAEL missing	NOAEL missing	NOEL missing
SODIUM SULFATE	LD50 missing	267857	NOAEL missing	8933036	No evidence	Negative	NOEL missing	NOEL missing	13392857	37500000	5357143
SODIUM BICARBONATE	LD50 missing	1873	NOAEL missing	NOAEL missing	NOEL missing	Negative	NOEL missing	NOEL missing	NOAEL missing	15089	No evidence

Toxicological evaluation - Safety Assessment



1. IDENTIFICATION OF THE PRODUCT

Product name : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
 Formula code : KOC-002
 Issue date : 24-03-2016

2. SAFETY ASSESSMENT

INCI name	Within Annex	Acute dermal toxicity	(Sub)Chronic dermal toxicity	Skin Sensitisation	Mutagenicity	Carcinogenity	Reprotoxicity (fertility)	Reprotoxicity (development)	INFO CARE Expertise	Assess-ment	Conclusion
SODIUM FERROCYANIDE		133214920	> 1000	No evidence	NOEL missing	Negative	NOEL missing	> 1000			Safe
SODIUM SULFATE		> 1000	> 1000	No evidence	> 1000	Negative	> 1000	> 1000			Safe
CI 15985	No	> 1000	> 1000	No evidence	NOEL missing	Negative	> 1000	> 1000		Reviewed	Safe
CI 45430; ACID RED 51	No	> 100	> 1000	No evidence	No evidence	Negative	> 1000	NOEL missing		Reviewed	Safe
METHYLPARABEN	Yes	> 1000	> 1000	No evidence	No evidence	Negative	NOEL missing	> 1000			Safe
SODIUM BICARBONATE		> 100	NOEL missing	No evidence	No evidence	Negative	NOEL missing	> 1000			Safe
CI 19140; ACID YELLOW 23	No	> 1000	> 1000	No evidence	> 1000	Negative	No evidence	> 1000		Reviewed	Safe
CI 42090; ACID BLUE 9	No	> 1000	> 1000	> 300	No evidence	Negative	> 1000	No evidence		Reviewed	Safe
SODIUM CHLORIDE		650	> 1000	No evidence	No evidence	Negative	NOEL missing	NOEL missing			Safe
TRICALCIUM PHOSPHATE		> 100	> 100	No evidence	NOEL missing	Not mutagenic	> 1000	> 1000			Safe
ZEA MAYS STARCH		LD50 missing	NOEL missing	No evidence	NOEL missing	Missing	NOEL missing	NOEL missing			Safe

ANNEX I: CV Safety Assessor



1. SAFETY ASSESSOR

Name : Ing. J.M. van de Hoef - van Veldhuizen
Position : Senior Cosmetic Safety Officer
Company : INFO CARE B.V.
Telephone : +31 30 6620235

2. QUALIFICATION

Training and Education : Bachelor degree in organic and analytical/physical chemistry, Hogere Laboratoriumschool Amersfoort, 1987 Diploma in Cosmetic Science, Society of Cosmetic Scientists, 1992 10 Years experience in product development of cosmetic products and experience in consumer product legislation as from 1998.
Memberships : NVCC (Dutch Association for Cosmetic Chemists)
Other :

3. COMPANY PROFILE

Company name : INFO CARE B.V.
Address : Tiberiusweg 9
3453 KZ DE MEERN,
Telephone : +31 30 6620235
Fax : +31 30 6620236
E-mail : cvandehoef@info-care.nl
Website : www.info-care.nl
Founded : 01-01-1999
Core business : Consultancy in safety and regulatory affairs with regard to dangerous substances, dangerous preparations and cosmetics

ANNEX I: CV Safety Assessor



1. SAFETY ASSESSOR

Name	: Drs. J.C.J. van Wegen
Position	: General Manager
Company	: INFO CARE B.V.
Telephone	: +31 30 6620235

2. QUALIFICATION

Training and Education	: University degree in Organic Chemistry with a specialisation in organo-metallic chemistry, University of Utrecht, February 1989. Safety Assessment of Cosmetics in the EU, University of Brussels, April 2002. Experience in product development of consumer products and consumer product legislation as from 1991.
Memberships	: NAV (Dutch Aerosol Association) NCV (Dutch Cosmetics Association) NVCC (Dutch Association for Cosmetic Chemists) SEPAWA (Dutch Branch of German Seife Parfum und Wachse Association)
Other	: Trainer at 'Product Development in Cosmetics', PAON, February 2003. Trainer for SBA - Aromtherapie (Helicon opleidingen), 2005, resp. 2006 Trainer at 'Cosmetica: Wetgeving & Veiligheidsbeoordeling', NCV 2011.

3. COMPANY PROFILE

Company name	: INFO CARE B.V.
Address	: Tiberiusweg 9 3453 KZ DE MEERN,
Telephone	: +31 30 6620235
Fax	: +31 30 6620236
E-mail	: jvanwegen@info-care.nl
Website	: www.info-care.nl
Founded	: 01-01-1999
Core business	: Consultancy in safety and regulatory affairs with regard to dangerous substances, dangerous preparations and cosmetics

3. Method of manufacture and a statement of GMP compliance



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. MANUFACTURING METHOD

No documents attached.

3. GMP COMPLIANCE

See enclosed.

4. Proof of effect for the product



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. CLAIMS

No claims for this product.

5. Data on animal testing



1. IDENTIFICATION OF THE PRODUCT

Product name	: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
Formula code	: KOC-002
Issue date	: 24-03-2016

2. ANIMAL TESTING ON COSMETIC PRODUCT

Tests on finished product	: None.
Tests on prototype(s)	: None.

3. ANIMAL TESTING ON RAW MATERIALS

Tests on raw materials	: To the best of our knowledge this product does not contain substances which are tested on animals to prove the safety in use in cosmetic applications.
------------------------	--