



KINGDOM of COLORS



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

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Product Information File

Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple (KOC-002)

Composed by INFO CARE BV by order of Kingdom of Colors BV, Mastwijkerdijk 108E, 3417 BT Montfoort, Nederland

Date of issue: 08-04-2016

INFO CARE B.V.

A handwritten signature in black ink, appearing to read 'J.C.J. van Wegen', is written over a horizontal line.

Drs. J.C.J. van Wegen

Kingdom of Colors BV
Mastwijkerdijk 108E
3417 BT Montfoort
Nederland
Tel: +31-6 248 14331

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

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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 | : Mastwijkerdijk 108E |
| Place/Country | : Montfoort |
| Telephone | : +31-6 248 14331 |



Cosmetic Product Safety Report

Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple (KOC-002)

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Cosmetic Product Safety Report

PART A: COSMETIC PRODUCT SAFETY INFORMATION

Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple (KOC-002)

Composed by INFO CARE BV by order of Kingdom of Colors BV, Mastwijkerdijk 108E, 3417 BT Montfoort, Nederland

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Drs. J.C.J. van Wegen

1. Quantitative and qualitative composition



1. IDENTIFICATION OF THE PRODUCT

| | |
|--------------|--|
| Product name | : Holi Color Powder |
| Formula code | : Red/Green/Blue/Orange/Pink/Yellow/Purple |
| Issue date | : KOC-002 |
| | : 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 | ZEA MAYS STARCH | 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 |
| Sodium Chloride IP | SODIUM CHLORIDE | 7647-14-5 | 231-598-3 | Ingredient | / oral care 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 dying |
| 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) | METHYLPARABEN | 99-76-3 | 202-785-7 | Ingredient | preservative |

2. Physical / Chemical Characteristics And Stability



1. IDENTIFICATION OF THE PRODUCT

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

2. FORMULA SPECIFICATIONS

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

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 | Formula code | Issue date | : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple : KOC-002 : 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 | Formula code | Issue date | : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple : KOC-002 : 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 | Formula code | Issue date | : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple : KOC-002 : 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 | Formula code | Issue date | : Holi Color Powder |
| | | | Red/Green/Blue/Orange/Pink/Yellow/Purple |
| | | | : KOC-002 |
| | | | : 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 | cm ² |
| 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 | Formula code | Issue date | : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple |
| | | | : KOC-002 |
| | | | : 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 Formula code Issue date : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
: KOC-002
: 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

| | | | |
|--------------|--------------|------------|--|
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| | | | : KOC-002 |
| | | | : 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 Formula code Issue date : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
: KOC-002
: 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 | Formula code | Issue date | : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple |
| | | | : KOC-002 |
| | | | : 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 Formula code Issue date

: Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple
: KOC-002
: 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

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

2. HEALTH RELATED COMPLAINTS

Total complaints (%) Health related Complaints / incidents

| |
|--|
| : 0 |
| : 0% of marketed value |
| : 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 | Formula code | Issue date | : Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple : KOC-002 : 24-03-2016 |
|--------------|--------------|------------|--|

2. OTHER INFORMATION



Cosmetic Product Safety Report

PART B: COSMETIC PRODUCT SAFETY ASSESSMENT

Holi Color Powder Red/Green/Blue/Orange/Pink/Yellow/Purple (KOC-002)

Composed by INFO CARE BV by order of Kingdom of Colors BV, Mastwijkerdijk 108E, 3417 BT Montfoort, Nederland

Date of issue: 08-04-2016

INFO CARE B.V.

A handwritten signature in black ink, appearing to read 'J.C.J. van Wegen', is written over a horizontal line.

Drs. J.C.J. van Wegen

1. Assessment conclusion



1. IDENTIFICATION OF THE PRODUCT

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

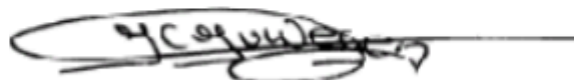
Signature :



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 |
| Formula code | : Red/Green/Blue/Orange/Pink/Yellow/Purple |
| Issue date | : KOC-002 |
| | : 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

| | | | |
|--|--|---|---|
| <p>For products sold in Germany : and/or Austria</p> |  <p>minimum dimensions 6x6 mm</p> | <p>For products sold in France and/or Belgium</p> | <p>:</p>  <p>minimum dimensions 6x6 mm</p> |
|--|--|---|---|

3. Reasoning

1. IDENTIFICATION OF THE PRODUCT

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

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

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

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|--------------|--------------|------------|--|
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| | | | : KOC-002 |
| | | | : 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 | NOAEL missing | | Reviewed | Safe |
| METHYLPARABEN | Yes | > 1000 | > 1000 | No evidence | No evidence | Negative | NOAEL missing | > 1000 | | | Safe |
| SODIUM BICARBONATE | | > 100 | NOAEL missing | No evidence | No evidence | Negative | NOAEL 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 | NOAEL missing | NOAEL missing | | | Safe |
| TRICALCIUM PHOSPHATE | | > 100 | > 100 | No evidence | NOEL missing | Not mutagenic | > 1000 | > 1000 | | | Safe |
| ZEA MAYS STARCH | | LD50 missing | NOAEL missing | No evidence | NOEL missing | Missing | NOAEL missing | NOAEL 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 Formula code Issue date

: Holi Color Powder

Red/Green/Blue/Orange/Pink/Yellow/Purple

: KOC-002

: 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 Formula code Issue date

: Holi Color Powder

Red/Green/Blue/Orange/Pink/Yellow/Purple

: KOC-002

: 24-03-2016

2. CLAIMS

No claims for this product.

5. Data on animal testing



1. IDENTIFICATION OF THE PRODUCT

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