

# Technical Data Sheet

## ICE

### General Description

- Daylight and ultra-violet responsive fluorescent pigments for water, solvent and oil based cosmetic applications.
- A dyed/pigmented thermoset polyester-amid polymer technology.

### Product Features

- ICE is designed for use in a wide range of cosmetic formulations, exhibiting very bright colors.
- Revolutionary new thermosetting polymer component, resistant to dissolution by solvents commonly employed in cosmetics.
- As a result of the cross-linked nature of these materials, formulations have to be processed at temperatures < 80°C.
- Recommended to use in slightly acidic and neutral conditions, not in alkaline conditions.
- Easy dispersible.

### Physical properties

Delivery form	Powder
Hegman grind	5 – 6

(1)Test methods and Certificate of Analysis (COA) available on request.

### Standard Colors

Product Name	Description
ICE-0-1192US	Chartreuse
ICE-0-1203EC	Chartreuse
ICE-3-1201US	Orange
ICE-3-1205EC	Orange
ICE-5-1206	Red
ICE-7-1196	Pink
ICE-8-1197	Magenta
ICE-8-1202*	Purple Magenta
ICE-9-1198*	Violet Blue
ICE-9-1199*	Blue

### Conventional Colors

ICE-0-1194US*	Yellow
ICE-0-1204EC*	Yellow

US: Allowed on the American market  
 EC: Allowed on the European Market  
 \*Non fluorescent colors/no UV response

### Packaging:

1 box = 5kg (1x5kg)  
 1 box = 20kg (1x20kg)  
 MOQ = 5kg

### Storage & shelf life:

120 months when kept in closed original packaging in a dry place at ambient temperature.

### Safety & regulatory:

Safety Data Sheet available on request.

### Identification Data

INCI name	Isophorone Diamine, Isophthalic Acid, Tromethamine Copolymer (CAS N° 1109229-52-8)
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### Formulation fluorescent colors

Product name	Description	INCI Name	CAS N°	C.I. Number	% <sup>(2)</sup>	Polymer <sup>(1)(2)</sup> %
ICE-0-1192US	Chartreuse	D&C Yellow 8	518-47-8	C.I. 45350	2.00	97.50
		D&C Yellow 10	8004-92-0	C.I. 47005	0.50	
ICE-0-1203EC	Chartreuse	D&C Yellow 8	518-47-8	C.I. 45350	2.00	97.38
		Yellow E104	8004-92-0	C.I. 47005	0.62	
ICE-3-1201US	Orange	D&C Red 22	17372-87-1	C.I. 45380	0.13	96.99
		D&C Red 28	18472-87-2	C.I. 45410	0.38	
		D&C Yellow 8	518-47-8	C.I. 45350	2.00	
		D&C Yellow 10	8004-92-0	C.I. 47005	0.50	
ICE-3-1205EC	Orange	D&C Yellow 8	518-47-8	C.I. 45350	2.00	96.90
		D&C Red 22	17372-87-1	C.I. 45380	0.12	
		D&C Red 28	18472-87-2	C.I. 45410	0.37	
		Yellow E104	8004-92-0	C.I. 47005	0.61	
ICE-5-1206	Red	FD&C Yellow 5	1934-21-0	C.I. 19140	0.28	97.24
		D&C Yellow 8	518-47-8	C.I. 45350	0.68	
		D&C Red 28	18472-87-2	C.I. 45410	1.80	
ICE-7-1196	Pink	D&C Red 22	17372-87-1	C.I. 45380	0.40	98.20
		D&C Red 28	18472-87-2	C.I. 45410	0.80	
		D&C Yellow 8	518-47-8	C.I. 45350	0.60	
ICE-8-1197	Magenta	D&C Red 22	17372-87-1	C.I. 45380	0.10	97.99
		D&C Red 28	18472-87-2	C.I. 45410	1.91	
ICE-8-1202	Purple	D&C Red 28	18472-87-2	C.I. 45410	1.90	97.78
		Ext D&C Violet 2	4430-18-6	C.I. 60730	0.32	
ICE-9-1198	Violet Blue	Ext D&C Violet 2	4430-18-6	C.I. 60730	2.00	98.00
ICE-9-1199	Blue	FD&C Blue 1	3844-45-9	C.I. 42090	1.00	99.00

<sup>(1)</sup> INCI Name: Isophorone Diamine/Isophthalic Acid/Tromethamine Copolymer (CAS N° 1109229-52-8)

<sup>(2)</sup> Actual percentages may vary slightly due to weighing tolerances in manufacturing.

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All colors may contain traces of propylene glycol, diethylhexyl sodium sulfosuccinate and sodium sulphate, which are present due to unavoidable impurities during manufacturing, according to GMP.

The certificate numbers of the used FDA certified cosmetic dyes are mentioned on the Certificate Of Analysis.

For some colors, additional certified dyes may be included (< 0.20%) to make small color corrections needed to correct unavoidable color differences within the certified cosmetic dyes. This will insure a more consistent color. Applicable D&C dyes used for color corrections: D&C Red 22, Ext. D&C Violet 2, FD&C Yellow 5, D&C Yellow 8, FD&C Blue 1.

#### Formulation conventional colors

Product name	Description	INCI Name	CAS N°	C.I. Number	%	Polymer <sup>(1)(2)</sup> %
<b>ICE-0-1194US</b>	Yellow	D&C Yellow 10	8004-92-0	C.I. 47005	15.00	85.00
<b>ICE-0-1204EC</b>	Yellow	Yellow E104	8004-92-0	C.I. 47005	17.75	82.25

<sup>(1)</sup> INCI Name: Isophorone Diamine/Isophthalic Acid/Tromethamine Copolymer (CAS N° 1109229-52-8)

<sup>(2)</sup> Actual percentages may vary slightly due to weighing tolerances in manufacturing.

All colors may contain traces of propylene glycol, diethylhexyl sodium sulfosuccinate, sodium sulphate and hydrochloric acid, which are present due to unavoidable impurities during manufacturing, according to GMP.

The certificate numbers of the used FDA certified cosmetic dyes are mentioned on the Certificate Of Analysis.

#### Field of application

For determination of the field of applications of ICE, please take into account the application area of the colorant/color additives (see PART A) and the toxicological tests of the polymer matrix (see PART B). The field of application remains the responsibility of the manufacturer of the cosmetic article.

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### PART A: Colorant/color additives

Product name	Description	Colorant/color additives	EU <sup>(1)</sup>	FDA <sup>(2)</sup>			
				Eye	Lip	Ext.	
ICE-0-1192US	Chartreuse	D&C Yellow 8	C.I. 45350	1*	No	No	Yes
		D&C Yellow 10	C.I. 47005	-	No	Yes	Yes
ICE-0-1203EC	Chartreuse	D&C Yellow 8	C.I. 45350	1*	No	No	Yes
		Yellow E104	C.I. 47005	1	No	No	No
ICE-3-1201US	Orange	D&C Red 22	C.I. 45380	1*	No	Yes	Yes
		D&C Red 28	C.I. 45410	1	No	Yes	Yes
		D&C Yellow 8	C.I. 45350	1*	No	No	Yes
		D&C Yellow 10	C.I. 47005	-	No	Yes	Yes
ICE-3-1205EC	Orange	D&C Yellow 8	C.I. 45350	1*	No	No	Yes
		D&C Red 22	C.I. 45380	1*	No	Yes	Yes
		D&C Red 28	C.I. 45410	1	No	Yes	Yes
		Yellow E104	C.I. 47005	1	No	No	No
ICE-5-1206	Red	D&C Red 28	C.I. 45410	1	No	Yes	Yes
		D&C Yellow 8	C.I. 45350	1*	No	No	Yes
		FD&C Yellow 5	C.I. 19140	1	Yes	Yes	Yes
ICE-7-1196	Pink	D&C Red 22	C.I. 45380	1*	No	Yes	Yes
		D&C Red 28	C.I. 45410	1	No	Yes	Yes
		D&C Yellow 8	C.I. 45350	1*	No	No	Yes
ICE-8-1197	Magenta	D&C Red 22	C.I. 45380	1*	No	Yes	Yes
		D&C Red 28	C.I. 45410	1	No	Yes	Yes
ICE-8-1202	Purple	D&C Red 28	C.I. 45410	1	No	Yes	Yes
		Ext. D&C Violet 2	C.I. 60730	3	No	No	Yes
ICE-9-1198	Violet blue	Ext. D&C Violet 2	C.I. 60730	3	No	No	Yes
ICE-9-1199	Blue	FD&C Blue 1	C.I. 42090	1	Yes	Yes	Yes

Product name	Description	Colorant/color		EU <sup>(1)</sup>	FDA <sup>(2)</sup>		
					Eye	Lip	Ext.
ICE-0-1194US	Yellow	D&C Yellow 10	C.I. 47005	-	No	Yes	Yes
ICE-0-1204EC	Yellow	Yellow E104	C.I. 47005	1	No	No	No

<sup>(1)</sup> Europe:

Radiant Color NV hereby declares, to the best of our knowledge, that the above mentioned ICE colors contain **colorants** (see table above) that are mentioned on Annex IV of the cosmetics regulation 1223/2009/EC and, according to our suppliers, meet the purity requirements thereof.

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1. Colouring agents allowed in all cosmetic products
2. Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of eyes, in particular eye make-up and eye make-up remover.
3. Colouring agents allowed exclusively in cosmetic products intended no to come into contact with the mucous membranes
4. Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

\* Not allowed if considered as hair dyes (safety assessment consulting) in hair dyeing products in the EU since 2009.

<sup>(2)</sup> FDA:

Radiant Color NV hereby declares, to the best of our knowledge, that the above mentioned ICE colors contain **color additives** (see table above) that may be used in different types of cosmetics, as provided for in Title 21 of the Code of Federal Regulations (CFR), Subpart C of Part 74 (Listing of Color Additives Subject to Certification) and Subparts B, C, and D of Part 82 (Listing of Certified Provisionally Listed Colors and Specifications).

## PART B: Toxicological test of polymer matrix

### General Tests data

Analysis following Ph. Eur. IV - 2.6.12 and 2.6.13 are carried out on every lot and results are reported on the COA. All other tests mentioned below have been done at Notox B.V., 's-Hertogenbosch, The Netherlands before March 11, 2009.

JMAFF stands for the Japanese Ministry of Agriculture, Forestry, and Fisheries.

The studies described have been correctly reported and were conducted in compliance with:

The Organization for Economic Cooperation and Development (OECD) Good Laboratory Practice Guidelines (1997), which essentially conform to:

The United States Food and Drug Administration Good Laboratory Practice Regulations.

The United States Environmental Protection Agency Good Laboratory Practice Regulations.

All tests have been done on ICE-Y-0940 colorless, lot P50601, which we confirm herewith to be a representative batch for Isophorone Diamine/Isophthalic Acid/ Tromethamine Copolymer .

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#### PRIMARY SKIN IRRITATION/CORROSION STUDY IN THE RABBIT

The study was carried out based on the guidelines described in: OECD No.404, "Acute Dermal Irritation/Corrosion" (2002); EC, No 440/2008, B4: "Acute Toxicity: Dermal Irritation/Corrosion"; US EPA, OPPTS 870.2500 (1998) Acute Dermal Irritation and JMAFF Guidelines (2000) including the most recent partial revisions.

Based on these results ICE-Y-0940 does not have to be classified and has no obligatory labeling requirement for skin irritation according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) of the United Nations (2007) and EC criteria for classification and labeling requirements for dangerous substances and preparations (Council Directive 67/548/EEC).

#### ACUTE EYE IRRITATION/CORROSION STUDY IN THE RABBIT

The study was carried out based on the guidelines described in: OECD No.405 (2002) "Acute Eye Irritation / Corrosion"; EC, No 440/2008, B5: "Acute Toxicity: Eye Irritation/Corrosion"; EPA, OPPTS 870.2400 (1998): "Acute Eye Irritation" and JMAFF guidelines (2000); including the most recent partial revisions.

Based on these results ICE-Y-0940 does not have to be classified and has no obligatory labeling requirement for eye irritation according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) of the United Nations (2007) and EC criteria for classification and labeling requirements for dangerous substances and preparations (Council Directive 67/548/EEC).

#### ASSESSMENT OF ACUTE DERMAL TOXICITY IN THE RAT

The study was carried out based on the guidelines described in: OECD No.402 (1987) "Acute Dermal Toxicity"; Commission Regulation (EC) (2008) No 440/2008, B.3: "Acute Toxicity (Dermal)"; EPA, OPPTS 870.1200 (1998), "Acute Dermal Toxicity" and JMAFF Guidelines (2000), including the most recent revisions.

The dermal LD50 value of ICE-Y-0940 in Wistar rats was established to exceed 2000 mg/kg body weight.

Based on these results ICE-Y-0940 does not have to be classified and has no obligatory labeling requirement for dermal toxicity according to the EC criteria for classification and labeling requirements for dangerous substance and preparations (Council Directive 67/548/EEC). Considering the evident toxicity observed (clinical signs and mortality) and according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) of the United Nations (2007), ICE-Y-0940 may be harmful in contact with skin (Category 5) for acute toxicity via the dermal route. Category 5 is not acknowledged in the EU, for this the given threshold in Category 5 of the GHS can't be tested in the EU.

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#### **ASSESSMENT OF ACUTE ORAL TOXICITY IN THE RAT (ACUTE TOXIC CLASS METHOD)**

The study was carried out based on the guidelines described in: OECD No.423 (2001) "Acute Oral Toxicity, Acute Toxic Class Method"; Commission Regulation (EC) No 440/2008, B1 tris: "Acute Oral Toxicity, Acute Toxic Class Method"; EPA, OPPTS 870.1100 (2002), "Acute Oral Toxicity" and JMAFF guidelines (2000) including the most recent partial revisions.

The oral LD50 value of ICE-Y-0940 in Wistar rats was established to exceed 2000 mg/kg body weight.

According to the OECD 423 test guideline the LD50 cut-off value was considered to exceed 5000 mg/kg body weight. Based on these results ICE-Y-0940 does not have to be classified and has no obligatory labeling requirement for oral toxicity according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) of the United Nations (2007) and EC criteria for classification and labeling requirements for dangerous substances and preparations (Council Directive 67/548/EEC).

#### **ASSESSMENT OF CONTACT HYPERSENSITIVITY IN THE MOUSE (LOCAL LYMPH NODE ASSAY)**

The study was carried out based on the guidelines described in: OECD, Section 4, Health Effects, No.429 (2002); EC, No 440/2008; B42: "Skin Sensitization: Local Lymph Node Assay" and EPA, OPPTS 870.2600 (2003) "Skin Sensitization".

Since there was no indication that the test substance elicit an SI  $\geq 3$  when tested up to 50%, ICE-Y-0940 was considered to be anon skin sensitizer. Based on these results ICE-Y-0940 does not have to be classified and has no obligatory labeling requirement for sensitization by skin contact according to the:

Globally Harmonized System of Classification and Labeling of Chemicals (GHS) of the United Nations (2007), EC criteria for classification and labeling of dangerous substances and preparations (Council

Directive 67/548/EEC and all adaptations to technical progress and amendments of this Directive published in the Official Journal of the European Communities).

#### **EVALUATION OF THE MUTAGENIC ACTIVITY IN THE SALMONELLA TYPHIMURIUM REVERSE MUTATION ASSAY AND THE ESCHERICHIA COLI REVERSE MUTATION ASSAY (WITH INDEPENDENT REPEAT)**

The study was carried out based on the most recent OECD and EC guidelines (compare for example No.471).

Based on the results of this study it is concluded that ICE-Y-0940 is not mutagenic in the Salmonella typhimurium reverse mutation assay and the Escherichia coli reverse mutation assay.

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