

## PRODUCT SPECIFICATION

**Product Code:** 85G53694

**Product Description:** OPADRY® II COMPLETE FILM COATING SYSTEM 85G53694 ORANGE

**Material Description:** Orange Powder

SPECIFICATION			
TEST	MINIMUM	MAXIMUM	TEST METHOD
COLOR DIFFERENCE DE	0.0	2.5 CIELAB Units Or Visual Match	GLO-QC-TM-0576/D05
COLOR DIFFERENCE VISUAL	COMPARES		GLO-QC-TM-0576
ASH	29.80	40.30 %	GLO-QC-TM-0699
APPEARANCE	ORANGE POWDER		GLO-QC-TM-0733
DISPERSION	PASS		GLO-QC-TM-0729
IR SCAN	COMPARES		GLO-QC-TM-0744

### SPECIAL TEST COMMENTS :

COLOR DIFFERENCE DE: Color acceptance is based on both instrumental and visual assessments. Occasionally, conflicting results may occur and after further assessment, material may be released with a DE above the limit. Standards should be established from either the first batch received or a batch, which has produced acceptable product in your process.

### ADDITIONAL INFORMATION

#### OPTIONAL IDENTIFICATION TEST :

IDENTIFICATION A	IR SCAN	COMPARES	GLO-QC-TM-0744
IDENTIFICATION B	FILM FORMATION	FILM FORMS	GLO-QC-TM-0745

### STORAGE CONDITIONS :

Seal container tightly. Keep at 30C/86F or less. Avoid high humidity.

### RE-EVALUATION PERIOD :

The re-evaluation period for this product is **365 DAYS** from the date of manufacture. Use after this period may be possible if appropriate re-evaluation indicates acceptability, however, Colorcon, Inc cannot warrant the use of the product beyond the re-evaluation period.

The information contained in this document is proprietary to Colorcon, Inc and may not be used or disseminated inappropriately.

Global Headquarters

Colorcon  
275 Ruth Rd, Harleysville, PA 19438  
Tel: +1 215.256.7700 Fax: +1 215.256.7799 Website: [www.colorcon.com](http://www.colorcon.com)

© BPSI Holdings LLC,2021. All trademarks, except where noted, are property of BPSI Holdings LLC.

Issued Date: 8-Nov-24  
Page 1 of 4



---

## PRODUCT SPECIFICATION

### WARRANTY STATEMENT :

Colorcon, Inc warrants that its products will meet the specifications expressly made a part of its sales contract during the stated re-evaluation period, provided the product is stored in a manner consistent with recommended storage conditions. Except for the warranty against patent infringement provided below, the foregoing warranty is exclusive and in lieu of all other warranties with respect to Colorcon, Inc products, whether express or implied, including without limitation, any implied warranty of merchantability or fitness for a particular purpose. In no event will Colorcon, Inc be liable for any indirect, incidental, special or consequential damages, in connection with or arising out of the furnishing, performance or use of Colorcon, Inc products.

The user of this product is responsible for determining the terms and conditions of regulatory approval of use and other aspects of suitability of these products for the user's intended use.

Based on current knowledge Colorcon, Inc is unaware that any of its products infringe any patent on a worldwide basis, except on selected occasions where the composition has been defined by the client. Colorcon, Inc does not warrant that the use of its products, or articles made therefrom, either alone or in conjunction with other materials will not infringe a patent.

The information contained in this document is proprietary to Colorcon, Inc and may not be used or disseminated inappropriately.

---

Global Headquarters

Colorcon  
275 Ruth Rd, Harleysville, PA 19438  
Tel: +1 215.256.7700 Fax: +1 215.256.7799 **Website: [www.colorcon.com](http://www.colorcon.com)**

© BPSI Holdings LLC, 2021. All trademarks, except where noted, are property of BPSI Holdings LLC.

**Issued Date: 8-Nov-24**  
**Page 2 of 4**



## PRODUCT SPECIFICATION

**Product Code:** 85G53694

**Product Description:** OPADRY® II COMPLETE FILM COATING SYSTEM 85G53694 ORANGE

Ingredients/Compendial Reference	Grade/Dye Strength	E Number	CFR Reference	CI Number
POLYVINYL ALCOHOL-PART. HYDROLYZED (USP,FCC,PhEur, JPE, ChP, GB)	4.8-5.8 mPas	E1203	-	-
TALC (USP, FCC, PhEur, JP,JECFA, ChP)	-	E553b	73.1550	-
MACROGOL/PEG (USP, FCC, PhEur, JECFA, JP)	MW 3350, MACROGO L 4000 JP	E1521	172.820	-
QUINOLINE YELLOW ALUMINUM LAKE (JECFA, GB)	18% - 24%	E104	-	47005
TITANIUM DIOXIDE (USP, FCC, PhEur, JP, JSFA, ChP, GB)	-	E171	73.575,73.157 5,73.2575	77891
LECITHIN (SOYA) (NF,JPE,FCC,JSFA,GB)	-	E322	184.1400	-
ERYTHROSINE ALUMINUM LAKE (JECFA, GB)	15%-18%	E127	-	45430:1
FD&C BLUE #2/INDIGO CARMINE ALUMINUM LAKE (JECFA, JP MO, GB)	3%-5%	E132	82.51,82.102	73015:1

The information contained in this document is proprietary to Colorcon, Inc and may not be used or disseminated inappropriately.

### Global Headquarters

Colorcon  
275 Ruth Rd, Harleysville, PA 19438  
Tel: +1 215.256.7700 Fax: +1 215.256.7799 Website: [www.colorcon.com](http://www.colorcon.com)

© BPSI Holdings LLC,2021. All trademarks, except where noted, are property of BPSI Holdings LLC.

**Issued Date: 8-Nov-24**  
**Page 3 of 4**



---

## PRODUCT SPECIFICATION

### Key

**CFR** - Code of Federal Regulations

**E number** - Purity Criteria according to Commission Regulation (EU) No 231/2012 for Food Additives

**JECFA** - Joint Evaluation Committee on Food Additives

**JP MO** - Japanese Ministerial Ordinance

**NF** - National Formulary

**CI** - Colour Index

**FCC** - Food Chemicals Codex

**JP** - Japanese Pharmacopoeia

**JSFA** - Japan's Specifications and Standards for Food Additives

**PhEur** - European Pharmacopoeia

**ChP** - Chinese Pharmacopoeia

**GB** - China National Standard

**JPE** - Japanese Pharmaceutical Excipients

**mPas** - milliPascal seconds

**USP** - United States Pharmacopoeia

**cP** - Centipoise

**IP** - Indian Pharmacopoeia

**JPED** - Japanese Pharmaceutical Excipient Directory

**MW** - Molecular Weight

The information contained in this document is proprietary to Colorcon, Inc and may not be used or disseminated inappropriately.

---

### Global Headquarters

Colorcon  
275 Ruth Rd, Harleysville, PA 19438  
Tel: +1 215.256.7700 Fax: +1 215.256.7799 **Website:** [www.colorcon.com](http://www.colorcon.com)

© BPSI Holdings LLC, 2021. All trademarks, except where noted, are property of BPSI Holdings LLC.

**Issued Date: 8-Nov-24**  
**Page 4 of 4**