OPULYN™ 301 Opacifier

Global Cosmetic Dossier

Version: 7

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The Dow Chemical Company
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IDENTIFICATION

Trade Name: OPULYN™ 301 Opacifier

INCI Name: Styrene/Acrylates Copolymer

CAS Registry Number: 9010-92-8

Molecular Weight: >1,000,000

Physical Form: Liquid

Function: Opacifying Agent

COMPOSITION

The composition shown below represents what is listed in Section 2 of the US MSDS. The minimum and maximum values presented in this table do not necessarily represent product specifications. Please see the "**Specifications**" section for the product specifications.

CONSTITUENT	CAS#	Min. %	Max. %	Function *	Feedstock Origin
Styrene/acrylic copolymer	9010-92-8	39.0	41.0	Key Ingredient	Synthetic
Water	7732-18-5	59.0	61.0	Solvent	Municipal
Residual monomers			< 500.0 ppm	Carryover	Synthetic

REGULATORY STATUS

Global Inventory Status

Country	Inventory / Registration	Status
Australia	Australian Inventory of Chemical Substances (AICS)	Complies[1]
Canada	Domestic Substances List (DSL)	Complies[1]
China	China Chemical Inventory	Complies[1]
European Union	European Inventory of Existing Chemical Substances (EINECS)	Exempt[2]
Japan	Ministry of International Trade and Industry (MITI)	Complies[1]
Korea	Korean Existing Chemical Substances (KECL)	Complies[1]
Philippines	Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Complies[1]
United States	Toxic Substances Control Act Inventory (TSCA)	Exempt[2]

[1] Complies – All components of the product comply with the respective inventory.

[2] Exempt - In Europe, the polymer in this product meets the definition of a polymer and is exempt from listing on the EINECS inventory. All other components of this product comply. In the United States, this product is exempt from TSCA if used only in cosmetic applications.

[3] Delayed - Rohm and Haas Company, A Wholly Owned Subsidiary of The Dow Chemical Company, has submitted a notification on an intentional component in this product and has received permission to import or manufacture in the applicable country. However, this intentional component will not be added to the country's inventory until some time in the future.

[4] Does Not Comply – One or more components of the product do not comply with the respective inventory. Restrictions on volume limits may apply.

[5] We have reviewed the composition of this product and conclude that none of the components, as described on our Material Safety Data Sheet (MSDS), are subject to any reporting requirements associated with rules or orders under Sections 4, 5, 6, 7, and 12b of TSCA.

Cosmetic Approvals

European Union
Complies with Council Directive 76/768/EEC and its 7th Amendment.

Japan
Permitted for use in cosmetic applications.

United States
Permitted for use in cosmetic applications, INCI name accepted.

OPULYN™ 301 Opacifier has been reviewed by the Cosmetic Ingredient Review Panel in the broad context of acrylate copolymers. An assessment of Acrylates copolymers was published in a CIR Panel report on December 21, 1999.

REACH Statement

We are committed to meeting our legal obligations under REACH as a manufacturer / importer / downstream user. We have pre-registered the substances in OPULYN™ 301 Opacifier as required under REACH. We currently intend to register these substances by the required registration deadline based on the import volume of our importing EU legal entity.

The polymer in OPULYN™ 301 Opacifier is exempt from the registration obligations under REACH as long as the monomers comprising the polymer at >2% by weight are registered. We have pre-registered and currently intend to register the required monomers that we import into the EU in the polymer component of OPULYN™ 301 Opacifier. We have also confirmed that our upstream monomer suppliers have pre-registered and currently intend to register the monomers comprising the personal care polymers that we manufacture in the EU. We do not anticipate an interruption in supply due to REACH.

OPULYN™ 301 Opacifier does not contain any of the substances currently on the Substances of Very High Concern (SVHC) list at ≥ 0.1%. We do not anticipate any components of this product to be added to the candidate list for authorization. OPULYN™ 301 Opacifier does not contain any persistent, bioaccumulative and toxic substances (PBT), any very persistent, very bioaccumulative and very toxic substances (vPBT), or any carcinogenic, mutagenic or reprotoxic substances (CMR) at ≥ 0.1%.

Please note, that the obligation to pre-register and register under REACH belongs to the entity which manufacturers or imports a substance into the EU at >1MT per year. Therefore, please consider whether you have any REACH obligation if you import substances into the EU. We refer you to http://echa.europa.eu to help you determine the relevant registration obligations for your products.

We also encourage you to visit our REACH website www.reach.dow.com where you will be able to find and download the most recent REACH related documents on our products.

CERTIFICATIONS

Raw Material Origin Certification

With regards to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE), we do not intentionally add, nor would we expect any component of OPULYN™ 301 Opacifier to be derived from bovine, ovine, caprine, porcine or related ingredients of animal origin. This product is derived from materials of synthetic, petrochemical and/or mineral origins. The manufacturing equipment for the product is not used for the manufacture of products of animal origin or products containing ingredients of animal origin. This product is not stored with products of animal origin or products containing ingredients of animal origin.

Kosher/Halal Certification

With regards to Halal and Kosher status, OPULYN™ 301 Opacifier is free of wheat, oat, barley or rye derivatives. Although this product has not been officially certified by a Rabbinical or Islamic council, we believe this product is judged to be “pareve” within the framework of the Jewish definition and permitted under Muslim standards. We are disclosing above information, to the best of knowledge based upon data from our raw material suppliers and our manufacturing process. Please note that we do not test any of the raw materials used in the product for the presence of the above mentioned substances.

Allergens Certification

OPULYN™ 301 Opacifier does not contain any of the eight major food allergens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat and/or soybeans) or proteins as listed in the FALCPA of 2004 and in FDA Guidance Sec.550.250 and does not contact these food allergen during the manufacturing process. OPULYN™ 301 Opacifier does not contain any of the 26 allergen ingredients as defined in the 7th Amendment of the European Cosmetics Directive. OPULYN™ 301 Opacifier is gluten-free.

CA Prop65 Certification

To the best of our knowledge, OPULYN™ 301 Opacifier does not contain any contaminants or by products known to the State of California to cause cancer or reproductive toxicity as listed under the Proposition 65 State Drinking Water and Toxic Enforcement Act.

CA SB484 Cosmetic Act Certification

To the best of our knowledge, OPULYN™ 301 Opacifier does not contain any components that would qualify for reporting under the California Safe Cosmetics Act of 2005 (SB 484).

VOC Certification

None of the Class 1, Class 2, and Class 3 Residual Solvents specified in USP General Chapter <467> effective on 1 JUL 2008 are used in the manufacture of OPULYN™ 301 Opacifier. Any available analyses of organic volatile impurities are listed in the **ANALYTICAL** section of this document.

Fragrance Materials Certification

OPULYN™ 301 Opacifier does not contain any fragrance materials.

Endocrine Disruptor Certification

To the best of our knowledge, OPULYN™ 301 Opacifier does not contain any potential endocrine disruptors.

CMR Certification

No substances classified as Carcinogenic, Mutagenic or toxic for Reproduction, of category 1,2, and 3 under Annex I to Directive 67/548/EEC are intentionally used in the manufacture of OPULYN™ 301 Opacifier.

Impurities Statement

To the best of our knowledge, OPULYN™ 301 Opacifier does not contain dioxin, glycol ethers, asbestos, organotin compounds, phthalates, azo dyes, acrylamide, nonyl phenol ethoxylates, or alkyl phenol ethoxylates. These substances are not intentionally added and are not expected to be generated during the manufacturing process. We do not expect these substances to be present in the raw materials used to produce OPULYN™ 301 Opacifier.

Clean Water Act Toxic Pollutant List Certification

To the best of our knowledge, OPULYN™ 301 Opacifier does not contain any components that are listed on the Clean Water Act Toxic Pollutant List in 40 CFR 401.15.

Clean Air Act Certification

To the best of our knowledge, with regards to the Clean Air Act, Section 112(b), OPULYN™ 301 Opacifier does not contain any Hazardous Air Pollutants (HAPs) at or above 0.1%.

To the best of our knowledge, OPULYN™ 301 Opacifier does not contain any components that are listed on the Clean Air Act Sec. 602 Class I and II Ozone Depleting Substances List (40 CFR 82).

RoHS Directive 2002/95/EC Certification

Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment requires that electrical and electronic equipment placed on the EU market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyl, polybrominated biphenyl ether.

Although OPULYN™ 301 Opacifier does not fall in the scope of this directive, it can be used as a raw material in the manufacture of some components of electrical and electronic equipment.

We hereby confirm that in the manufacture of OPULYN™ 301 Opacifier, we do not intentionally use polybrominated biphenyl or polybrominated biphenyl ether. Based upon data from our raw material suppliers and knowledge of the manufacturing process, we have no reason to believe that these substances are present.

Heavy metals analyses of OPULYN™ 301 Opacifier by Inductively Coupled Plasma Mass Spectroscopy (ICP/MS) showed that lead, mercury, and cadmium are not present with a Limit of Detection of less than 1 part per billion (ppb). Hexavalent chromium was not analyzed, but it is not expected to be found at greater than trace levels.

Shelf Life Certification

The shelf life for OPULYN™ 301 Opacifier is 600 days (20 months) from the date of manufacture provided on the Certificate of Analysis (COA) for each batch lot.

Manufacturing Location Certification

OPULYN™ 301 Opacifier is manufactured for the North American, Latin American, and Asian markets by The Dow Chemical Company at 3100 State Rd, Croydon, PA USA 19021.
OPULYN™ 301 Opacifier is manufactured for the European market by The Dow Chemical Company at Ringvägen 163, SE-26122 Landskrona, Sweden.

SPECIFICATIONS

COA Specifications

Appearance, as-is Milk-white fluid, free of coagulated gum and visible impurities

Solids content, % by wt. 39.00 – 41.00
(Dry 0.6 gram at 150°C for 20 minutes in a forced draft oven.)

pH 2.05 – 2.50

Viscosity, as is, cps 50, maximum
(Brookfield LV, spindle #1, 60 rpm, 25°C)

Gel particles on 150 micron screen, ppm 50, maximum

Gel particles on 45 micron screen, ppm after passing through 150 micron screen 100, maximum

FTIR Identity Conforms to reference

COA Microbiological Specifications

Method	Results
Aerobic Plate Count < 100 CFU/g	Pass / Fail
Absence of *Candida albicans* in 1 g	Pass / Fail
Absence of Gram Negative Bacteria	Pass / Fail
Absence of *Staphylococcus aureus* in 1 g	Pass / Fail

ANALYTICAL

Residual Monomer

Monomer	CAS-No.	Concentration	Comment
Styrene	100-42-5	≤ 20 ppm	

Heavy Metals

Metals were determined by Inductively Coupled Plasma Emission Spectroscopy.

Metal	CAS-No.	Results (ppm)	Limit of Detection (ppm)
Arsenic	7440-38-2	No detect	0.1
Cadmium	7440-43-9	No detect	0.1
Cobalt	7440-48-4	No detect	0.1
Chromium	7440-47-3	No detect	0.1
Copper	7440-50-8	No detect	0.1
Iron	7439-89-6	No detect	0.1
Mercury	7439-97-6	No detect	0.5
Nickel	7440-02-0	No detect	0.1
Lead	7439-92-1	No detect	0.1
Zinc	7440-66-6	No detect	0.1

By-Products and Impurities

Impurity	CAS-No.	Results (ppm)	Limit of Detection (ppm)
1,4-Dioxane*	123-91-1	No detect	0.5

TOXICOLOGY

Overall evaluation

The acrylic co-polymer in OPULYN™ 301 Opacifier was tested in number of non-clinical and clinical tests to evaluate potential hazards associated with handling and use of the material. Several tests were conducted with a material that varied slightly in monomer composition and percent solids however; there are no marked differences in these materials.

Acute Toxicity Profile

Toxicity data for compositionally similar acrylic co-polymers are below:

Test/Species	Results	GLP
Oral LD50 – rat	>5.0 g/kg	Yes
Dermal LD50 – rat	>2.0 g/kg	Yes
Skin irritation – rabbit	Not irritant (US, EEC)	Yes
Eye irritation – rabbit	Not irritant (US, EEC)	Yes

Genetic Toxicity Profile

Test/Species	Results	GLP
Ames Test	Not mutagenic with and without metabolic activation	Yes
In vitro cytogenetic	Not mutagenic with and without metabolic activation	Yes

Human Toxicity Profile

Test/Species	Results	GCP
21-day cumulative irritation	Non sensitizing and non-irritating	Yes

Animal Testing Statement

OPULYN™ 301 Opacifier was not tested in animals.

Ecotoxicity Profile

Ecotoxicity data for a compositionally similar acrylic co-polymer are below:

Test/Species	Results	GLP
Algae EC50 – 72 hr Algae NOEC– 72 hr	100 ppm, low concern * 100 ppm	Yes
Daphnia magna LC50 – 48 hr Daphnia magna NOEC– 48 hr	100 ppm, low concern * 100 ppm	Yes
Rainbow trout LC50 – 96 hr Rainbow trout NOEC – 96 hr	100 ppm, low concern * 100 ppm	Yes

* US EPA TSCA criteria

Environmental Fate Profile

Environmental fate data for a compositionally similar acrylic co-polymer are below:

Test/Species	Results	GLP
Inherent 25-day biodegradation	37% elimination (expressed as % DOC), bioeliminable via adsorptive processes	Yes
Activated sludge respiratory inhibition	EC50 > 100 mg/L, non-inhibitory to bacteria	Yes
Microtox bacteria assay	EC50 (15 min) = 824 ppm, practically non-toxic	Yes

Biodegradation

Acrylic polymers are generally stable materials and can almost be considered 'inert' in the environment. These materials do not readily decompose or biodegrade in the environment. While these polymers are non-biodegradable, they are bioeliminable. In other words, they are removed from environmental compartments where they could be available to aquatic organisms. The removal process is via rapid sorption to sediment, suspended solids and organic matter. This process makes the polymers less bioavailable thereby reducing toxicity further. Typically the molecular weight of these emulsion polymers is such that it precludes uptake by aquatic organisms and thus bioaccumulation is highly unlikely. The emulsion polymers are also generally non-toxic to activated sludge waste water systems and are considered bioeliminable in waste water treatment plants (via sorption to biosolids).

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