

Product Regulatory Information

DOW CORNING™ QP1-40 Liquid Silicone Rubber

1. General Information

Product Name: DOW CORNING™ QP1-40 Liquid Silicone Rubber

1.1. Scope of this Document

The purpose of this document is to provide key regulatory information frequently requested by customers on the above-mentioned products. The information contained herein is offered in good faith and is believed to be accurate as of the date shown below. However, because final conditions and methods of use of our products are beyond our control, this information should not be substituted for customer's own regulatory determinations and tests to ensure that the use of DuPont's products are legally compliant, safe, effective, and fully satisfactory for the customer's intended end use. For further information, please contact your local DuPont representative.

1.2. Other Information

These products are intended for fabrication of medical devices and device components for the healthcare industry, including those that will be implanted in humans for **not more than 29 days**. They are also appropriate for food contact applications.

2. Quality Information

To assure consistent quality for health care applications, DOW CORNING™ QP1-40 Liquid Silicone Rubber is manufactured, packaged, and tested at ISO 9001 registered facilities and are committed to Responsible Care practices.

3. Physicochemical Information

3.1. Type of Substance Mixture, sold as a Part A and a Part B

3.2. Main ingredients – this does not reflect a full composition and should not be used for regulatory registration purpose

Part A

CAS Number	Chemical Description	Weight Percent
68083-19-2	Dimethyl siloxane, dimethylvinyl-terminated	50 – 70
68988-89-6	Dimethylvinylated and trimethylated silica	30 – 50
68083-18-1	Dimethyl, methylvinyl siloxane, dimethylvinyl-terminated	1 – 5
	Platinum Catalyst	<0.1

Part B

CAS Number	Chemical Description	Weight Percent
68083-19-2	Dimethyl siloxane, dimethylvinyl-terminated	50 – 70
68988-89-6	Dimethylvinylated and trimethylated silica	30 – 50
68083-18-1	Dimethyl, methylvinyl siloxane, dimethylvinyl-terminated	1 – 5
68554-51-8	Dimethyl, methylhydrogen siloxane with methyl silsesquioxane	1 – 5

3.3. Source of ingredients	Synthetic
3.4. Physical Form	Paste (prior to cure)

4. Regulatory Information									
4.1. Compendial Compliance (cured material)									
	<table border="0"> <thead> <tr> <th>Regulation</th> <th>Compliance</th> </tr> </thead> <tbody> <tr> <td>USP/NF <88></td> <td>Class VI</td> </tr> <tr> <td>21 CFR 177.2600</td> <td>Formulation meets definition</td> </tr> <tr> <td>BfR, XV</td> <td>Meets requirements</td> </tr> </tbody> </table>	Regulation	Compliance	USP/NF <88>	Class VI	21 CFR 177.2600	Formulation meets definition	BfR, XV	Meets requirements
Regulation	Compliance								
USP/NF <88>	Class VI								
21 CFR 177.2600	Formulation meets definition								
BfR, XV	Meets requirements								
4.2. Precedence for Use	Product is used in medical devices.								
4.3. Allergens	A review of the production processes and ingredients indicated that the materials listed in 2011/1169/EU were not present. This includes cereals, crustaceans, eggs, fish, peanuts, soybeans, milk, other nuts, celery, mustard, sesame, sulphur dioxide and sulphites, lupins, and molluscs.								
4.4. Animal Derived Materials	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with ingredients of animal or human origin. We have not found materials derived from animals listed in EMA/410/01 rev. 3.								
4.5. Antibiotics	We do not intentionally formulate DOW CORNING™ QP1-40 Liquid Silicone Rubber with, nor are we aware that the product contains any substances considered to be antibiotics.								
4.6. Cytotoxins	We do not intentionally formulate DOW CORNING™ QP1-40 Liquid Silicone Rubber with, nor are we aware that the product contains any substances considered to be antineoplastic cytotoxins.								
4.7. GMO	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not derived from genetically modified organisms as defined in 1829/2003/EC and 1830/2003/EC.								
4.8. Genotoxic Impurities	DOW CORNING™ QP1-40 Liquid Silicone Rubber has not been chemically tested for genotoxic impurities. However, a review of the formulation and manufacturing conditions indicate that genotoxic impurities would not be present in detectable amounts.								
4.9. Hormones	We do not intentionally formulate DOW CORNING™ QP1-40 Liquid Silicone Rubber with, nor are we aware that the product contains any substances considered to be hormones produced by animals or plants.								
4.10. Residual Solvents	We have specifically audited and carefully monitor the process used								

to make DOW CORNING™ QP1-40 Liquid Silicone Rubber and have found no sources for the solvents specified in the Residual Solvents test outlined in the USP, Ph. Eur., or other compendial or regulatory lists including ICH Q3C and EMA/CHMP/ICH/82260/2006.

The introduction to the method states, “It is only necessary to test for residual solvents that are used or produced in the manufacture or purification processes of drug substances, excipients, or products.” Since our assessment has concluded that no potential sources for Class 1, 2, 3, those found in Table 4 or other organic solvents will be introduced into our product, we will continue our existing policy of not implementing this test for this product. We continue to monitor our processes on a periodic basis to maintain this assurance and implement the test requirement if needed.

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| 4.11. Metal catalyst and metal reagent residues | We have investigated the processes and raw materials used to make DOW CORNING™ QP1-40 Liquid Silicone Rubber but have found only one metal listed in Ph. Eur. 2.4.20 or 5.20, USP <231> or <232>, or EMEA/CHMP/SWP/4446/2000. As indicated in Section 3.2 General Composition, Platinum is added to Part A as a final cure catalyst. |
| 4.12. Metal Wastes | To the best of our knowledge and belief, lead, cadmium, mercury, and hexavalent chromium are not present at levels above those listed by the Council of Northeast Governors (CONEG) or as listed in European Directive 94/62/EC. |
| 4.13. Waste Electrical & Electronic Equipment (WEEE) | To the best of our knowledge and belief, the substances listed in Annex II of Directive 2002/96/EC are not present. |
| 4.14. Restriction of the Use of Certain Hazardous Substances in Electrical & Electronic Equipment (RoHS Directive) | To the best of our knowledge and belief, the substances prohibited in accordance with Directive 2011/65/EU and Directive 2015/863/EU are not normally expected to be present at or above the specified concentrations of 0.1% (by weight) for lead, mercury, hexavalent chromium, PBB, PBDE, (including decaBDE, PentaBDE or OctaBDE), Phtalates (including DEHP, BBP, DBP and DIBP) and 0.01% (by weight) for cadmium. |
| 4.15. Kosher/Halal Certification | DOW CORNING™ QP1-40 Liquid Silicone Rubber has not been reviewed by appropriate authorities to be certified as Kosher or Halal. |
| 4.16. Irradiation Treatment | DOW CORNING™ QP1-40 Liquid Silicone Rubber is not irradiated during production. |
| 4.17. Nanotechnology | Based on the EU Cosmetics Regulation (1223/2009/EC) and on the European Commission Recommendation on the Definition of |

Nanomaterial (2011/696/EU), we do not expect this product to be classified as a nanomaterial. This information is based on our knowledge available at this time.

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| 4.18. Bioburden/pyrogens | DOW CORNING™ QP1-40 Liquid Silicone Rubber is not specifically tested for bioburden or the presence of pyrogens on a lot to lot basis. |
| 4.19. California Proposition 65 | DOW CORNING™ QP1-40 Liquid Silicone Rubber is not known to contain any chemicals listed by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) as being known to cause cancer, birth defects or other reproductive harm. |
| 4.20. Substances of Very High Concern (SVHC) | Octamethylcyclotetrasiloxane (CAS 556-67-2), Decamethylcyclopentasiloxane (CAS 541-02-6) and Dodecamethylcyclohexasiloxane (CAS 540-97-6) may be present in silicone-based products as unavoidable impurities of the basic silicone polymer synthesis steps used by industry today. Levels present in this particular product are available upon request. |
| 4.21. Antioxidants | DOW CORNING™ QP1-40 Liquid Silicone Rubber does not contain added antioxidants. |
| 4.22. Pigments | DOW CORNING™ QP1-40 Liquid Silicone Rubber does not contain added pigments. |
| 4.23. Preservatives | DOW CORNING™ QP1-40 Liquid Silicone Rubber does not contain added preservatives. |
| 4.24. Aflatoxin | DOW CORNING™ QP1-40 Liquid Silicone Rubber has not been specifically tested for aflatoxin, but DOW CORNING™ QP1-40 Liquid Silicone Rubber is not expected to contain aflatoxin. |
| 4.25. Asbestos | DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate asbestos during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for asbestos content, we do not expect asbestos to be present. |
| 4.26. Bisphenol A (BPA)
CAS No. 80-05-7 | DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate BPA during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for BPA content, we do not expect BPA to be present in significant amounts. |
| 4.27. Butylated Hydroxyanisole (BHA) | DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate BHA during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for |

CAS No. 25013-16-5	BHA content, we do not expect BHA to be present in significant amounts.
4.28. Butylated Hydroxytoluene (BHT) CAS No. 128-37-0	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate BHT during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for BHT content, we do not expect BHT to be present in significant amounts.
4.29. Dioxin	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate dioxin during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for dioxin content, we do not expect dioxin to be present in significant amounts.
4.30. Ethylene Oxide	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made or treated with, nor does it generate ethylene oxide during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for ethylene oxide content, we do not expect ethylene oxide to be present.
4.31. Gluten	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with gluten.
4.32. <i>Jatropha</i>-derived Glycerin CAS No. 56-81-5	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with nor does it generate glycerin during processing. Upon inspection, we were not able to find sources of glycerin or other <i>Jatropha</i> derived materials that might be present in the processing equipment. Though we have not tested this product for glycerin or other <i>Jatropha</i> derived materials, we do not expect them to be present in significant amounts.
4.33. Lactose	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with lactose or other dairy products.
4.34. Latex	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with Natural Rubber/Latex.
4.35. Melamine	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not an “at risk” component as described in the FDA Guidance document. Nitrogen is not an ingredient, part of an ingredient, or measured in the material. Therefore, no Melamine Control Program is required. Even though we have not tested the material for melamine, we do not expect it to be present in significant amounts.
4.36. 2-Mercaptobenzothiazole (MBT) CAS No. 149-30-4	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate MBT during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for

	MBT content, we do not expect MBT to be present in significant amounts.
4.37. Palm Oil	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with palm oil or derivatives of palm oil.
4.38. Phthalates	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate phthalates during processing. Though we have not tested DOW CORNING™ QP1-40 Liquid Silicone Rubber for phthalate content, we do not expect phthalates to be present in significant amounts.
4.39. Polychlorinated Biphenyls (PCB)	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate PCB during processing. Though we have not tested the product for this material, we do not expect PCB to be present in significant amounts.
4.40. Polybrominated Biphenyls (PBB)	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate PBB during processing. Though we have not tested the product for this material, we do not expect PBB to be present in significant amounts.
4.41. EU Medical Devices Regulation (MDR (EU) 2017/745)	DOW CORNING™ QP1-40 Liquid Silicone Rubber is not made with, nor does it generate carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, or substances having endocrine-disrupting properties as defined in paragraph 10.4.1 of MDR (EU) 2017/745.

5. Biocompatibility Information

The tests listed have been performed and are warranted to meet the specification, but we do not test each lot. The test are performed in compliance with appropriate criteria provided in the following references:

Reference Number	Reference Name
ISO 10993-5 USP <87>	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-6	Biological evaluation of medical devices—Part 6: Tests for local effects after implantation
ISO 10993-10	Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity ANNEX B.2
ISO 10993-11 USP <151>	Biological evaluation of medical devices—Part 11: Tests for systemic toxicity
USP Plastic Class VI USP <88>	United States Pharmacopeia (USP) Biologic Reactivity Tests, <i>In Vivo</i>


6. Miscellaneous Product Information

6.1. Batch Numbering	Each batch is assigned a ten characters batch number related to the production plant, production date and production sequence. For example: A016AB1000
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6.2. Batch Definition	Each batch is a single production lot from the same raw materials in a single vessel.
6.3. Expiration Date	The expiration date for each uncured part is 18 months from the date of manufacture.
6.4. Storage Recommendations	<p>DOW CORNING™ QP1-40 Liquid Silicone Rubber should be stored between -20°C and 60°C (-4°F and 151°F) in the original unopened container.</p> <p>Product safety information required for safe use is not included in this document. Before handling, read the product and material safety data sheets (PSDS/MSDS) and container labels for safe use, physical and health hazard information. The PSDS/MSDS is available from your DuPont or Distributor sales representative.</p>

7. Revisions	
7.1. Current Version	7.0
7.2. Revision Date	1 July 2020
7.3. Supersedes Date	16 January 2019
7.4. Changes in most recent version	DuPont template, update section 3.2, 4.14 and add section 4.41

8. Contact DuPont
For further information, please consult your local DuPont representative.

9. DuPont Healthcare Product Steward

Sabine Springael

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