

## Product Regulatory Information

## Dow Corning® QP1 Bases JPN

## 1. General Information

## Product Names:

Dow Corning® QP1-25 Base JPN  
 Dow Corning® QP1-40 Base JPN  
 Dow Corning® QP1-55 Base JPN  
 Dow Corning® QP1-70 Base JPN

## 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 Dow Corning's products are legally compliant, safe, effective, and fully satisfactory for the customer's intended end use. For further information, please see our website, [www.dowcorning.com/healthcare](http://www.dowcorning.com/healthcare), or contact your local Dow Corning 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. Manufacturing, Packaging, and Release Site

Dow Corning Toray Co., Ltd.  
 Fukui Plant  
 Yachi  
 Awara-City, Fukui  
 Japan 919-0603

## 2.1. Site Quality System

To assure consistent quality for health care applications, Dow Corning QP1Bases JPN are manufactured, packaged, and tested at an ISO 9001 registered facility and is committed to Dow Corning Responsible Care practices.

## 3. Physicochemical Information

## 3.1. Type of Substance Mixture

## 3.2. General Composition

## CAS Number

68083-19-2

## Chemical Description

Dimethyl siloxane, dimethylvinyl-terminated  
 Treated silica

68083-18-1

Dimethyl, methylvinylsiloxane, hydroxyl-, vinyl-terminated

67923-19-7

Dimethyl, methylvinyl siloxane, dimethylvinyl-terminated

556-67-2

Dimethyl, methylvinyl siloxane, hydroxyl-terminated

Octamethylcyclotetrasiloxane

*Additional Component found in Dow Corning QP1-25 Base JPN*

70131-67-8

Dimethyl siloxane, hydroxyl-terminated

## Product Regulatory Information

## Dow Corning® QP1 Bases JPN

- |                            |              |
|----------------------------|--------------|
| 3.3. Source of ingredients | Synthetic    |
| 3.4. Physical Form         | Rubber-crepe |

## 4. Regulatory Information

## 4.1. Compendial Compliance

	Compendium	Monograph
	USP/NF	Class VI

- |                               |  |
|-------------------------------|--|
| 4.2. Precedence for Use       | Similar products used in the automotive and aerospace industries.  |
| 4.3. Allergens                | A review of the production processes and ingredients indicated that the materials listed in 2011/1169/EU were not present.   |
| 4.4. Animal Derived Materials | Dow Corning QP1 Bases JPN are not made with ingredients of animal or human origin.   |
| 4.5. Antibiotics              | Dow Corning Corporation does not intentionally formulate Dow Corning QP1 Bases JPN with, nor is Dow Corning aware that the products contain any substances considered to be antibiotics.   |
| 4.6. Cytotoxins               | Dow Corning Corporation does not intentionally formulate Dow Corning QP1 Bases JPN with, nor is Dow Corning aware that the products contain any substances considered to be antineoplastic cytotoxins  |
| 4.7. GMO                      | Dow Corning QP1 Bases JPN are not derived from genetically modified organisms as defined in 1829/2003/EC and 1830/2003/EC.   |
| 4.8. Genotoxic Impurities     | Dow Corning QP1 Bases JPN have 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                 | Dow Corning Corporation does not intentionally formulate Dow Corning QP1Bases JPN with, nor is Dow Corning aware that the products contain 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 Bases JPN and have found no sources for the solvents specified in the Residual Solvents test outlined in the USP 36, EP 8th edition, or other compendial or regulatory lists including ICH Q3C and EMA/CHMP/ICH/82260/ 2006. |



**Product Regulatory Information**  
**Dow Corning® QP1 Bases JPN**

	<p>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." 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 these products. We continue to monitor our processes on a periodic basis to maintain this assurance and implement the test requirement if needed.</p>
<b>4.11. Metal catalyst and metal reagent residues</b>	<p>We have investigated the processes and raw materials used to make Dow Corning QP1 Bases JPN but have not found significant sources of metals such as those listed in EP 2.4.20 or 5.20, USP &lt;231&gt; or &lt;232&gt;, or EMEA/CHMP/SWP/4446/2000. No metal catalysts or reagents are used in the material's process.</p> <p>The bases require a catalyst for final cure to occur, and platinum may be used to achieve this; Dow Corning® QP1 RD-27 Catalyst is available for use.</p>
<b>4.12. Kosher/Halal Certification</b>	<p>Dow Corning QP1 Bases JPN have not been reviewed by appropriate authorities to be certified as Kosher or Halal.</p>
<b>4.13. Irradiation Treatment</b>	<p>Dow Corning QP1 Bases JPN are not irradiated during production</p>
<b>4.14. Nanotechnology</b>	<p>Based on the EU Cosmetics Regulation (1223/2009/EC) and on the European Commission Recommendation on the Definition of Nanomaterial (2011/696/EU), Dow Corning does not expect these products to be classified as a nanomaterial. This information is based on our knowledge available at this time.</p>
<b>4.15. Bioburden/pyrogens</b>	<p>Dow Corning QP1 Bases JPN are not specifically tested for bioburden or the presence of pyrogens</p>
<b>4.16. California Proposition 65</b>	<p>Dow Corning QP1 Bases JPN are 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.</p>
<b>4.17. Substances of Very High Concern (SVHC)</b>	<p>As of the date of this declaration, Dow Corning Corporation does not intentionally formulate Dow Corning QP1 Bases JPN with, nor is Dow Corning aware that the products contain any SVHC as listed by the European Chemicals Agency.</p>
<b>4.18. Aflatoxin</b>	<p>Dow Corning QP1 Bases JPN have not been specifically tested for aflatoxin, but Dow Corning QP1 Bases JPN are not expected to</p>



## Product Regulatory Information

## Dow Corning® QP1 Bases JPN

	contain aflatoxin.
4.19. Antioxidants	Dow Corning QP1 Bases JPN do not contain added antioxidants.
4.20. Pigments	Dow Corning QP1 Bases JPN do not contain added pigments.
4.21. Preservatives	Dow Corning QP1 Bases JPN do not contain added preservatives.
4.22. <i>Jatropha</i> -derived Glycerin CAS No. 56-81-5	Dow Corning QP1 Bases JPN are not made with nor do they 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 these products for glycerin or other <i>Jatropha</i> derived materials, we do not expect them to be present in significant amounts.
4.23. Asbestos	Dow Corning QP1 Bases JPN are not made with, nor do they generate asbestos during processing. Though we have not tested Dow Corning QP1 Bases JPN for asbestos content, we do not expect asbestos to be present.
4.24. Gluten	Dow Corning QP1 Bases JPN are not made with gluten.
4.25. Latex	Dow Corning QP1 Bases JPN are not made with Natural Rubber/Latex
4.26. Melamine	Dow Corning QP1 Bases JPN are not “at risk” components 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 materials for melamine, we do not expect it to be present in significant amounts.
4.27. Bisphenol A (BPA) CAS No. 80-05-7	Dow Corning QP1 Bases JPN are not made with, nor do they generate BPA during processing. Though we have not tested Dow Corning QP1 Bases JPN for BPA content, we do not expect BPA to be present in significant amounts.
4.28. Dioxin	Dow Corning QP1 Bases JPN are not made with, nor do they generate dioxin during processing. Though we have not tested Dow Corning QP1 Bases JPN for dioxin content, we do not expect dioxin to be present in significant amounts.
4.29. Phthalates	Dow Corning QP1 Bases JPN are not made with, nor do they generate phthalates during processing. Though we have not tested Dow Corning QP1 Bases JPN for phthalate content, we do not

## Product Regulatory Information

## Dow Corning® QP1 Bases JPN

	expect phthalates to be present in significant amounts.
<b>4.30. Polychlorinated Biphenyls (PCB)</b>	Dow Corning QP1 Bases JPN are not made with, nor do they generate PCB during processing. Though we have not tested the products for this material, we do not expect PCB to be present in significant amounts.
<b>4.31. Polybrominated Biphenyls (PBB)</b>	Dow Corning QP1 Bases JPN are not made with, nor do they generate PBB during processing. Though we have not tested the products for this material, we do not expect PBB to be present in significant amounts.

## 5. BioCompatibility Information

The tests listed have been performed on cured material and met the specification, but Dow Corning does 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	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity (2009)
USP Plastic Class VI	United States Pharmacopeia (USP) Biologic Reactivity Tests, <i>In Vivo</i>

## 6. Miscellaneous Product Information

<b>6.1. Batch Numbering</b>	Each batch is assigned a ten digit batch number assigned in sequence from all products made in Dow Corning Corporation. For example: 0123456789
<b>6.2. Batch Definition</b>	Each batch is a single production lot from the same raw materials in a single vessel
<b>6.3. Expiration Date</b>	The expiration date is 15 months from the date of manufacture for: Dow Corning QP1-25 Base JPN Dow Corning QP1-40 Base JPN Dow Corning QP1-55 Base JPN. The expiration date is 12 months from the date of manufacture for: Dow Corning QP1-70 Base JPN
<b>6.4. Storage Recommendations</b>	Dow Corning QP1 Bases JPN should be stored below 32°C (90°F). 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 at <a href="http://www.dowcorning.com">www.dowcorning.com</a> or from your Dow Corning or Distributor sales representative.



## Product Regulatory Information

## Dow Corning® QP1 Bases JPN

## 6.5. Other materials available to cure elastomer

Dow Corning® QP1 RD-7 Cross Linker  
 Dow Corning® QP1 RD-9 Cure Controller  
 Dow Corning® QP1 RD-27 Catalyst

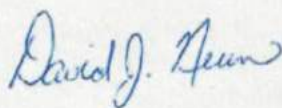
## 7. Revisions

7.1. Current Version	2.0
7.2. Revision Date	4 April 2014
7.3. Supersedes Date	19 Aug 2013
7.4. Changes in most recent version	Added sections 4.5, 4.6, 4.8, 4.9, 4.19, 4.20, 4.23, 4.24, 4.28, 9 Update 1.1, 4.3, 4.10

## 8. Contact Dow Corning

For further information, please see our Web site, [dowcorning.com](http://dowcorning.com), or consult your local Dow Corning representative.

## 9. Dow Corning Healthcare Steward



David J. Neun, Ph.D.

DISCLAIMER: THE INFORMATION CONTAINED HEREIN IS PROVIDED IN GOOD FAITH AND IS DEEMED ACCURATE AT THE DATE OF THIS LETTER BASED ON PRODUCT COMPOSITION AND VENDOR SUPPLIED INFORMATION. DOW CORNING DOES NOT TEST FOR COMPLIANCE. DOW CORNING MAKES NO WARRANTY EXPRESS OR IMPLIED ABOUT THIS INFORMATION. THE INFORMATION SHOULD NOT BE USED AS A SUBSTITUTE FOR CUSTOMER'S OWN TESTS AND ANALYSIS. CUSTOMER REMAINS RESPONSIBLE TO ENSURE THAT DOW CORNING'S PRODUCTS ARE FULLY SATISFACTORY FOR ITS INTENDED USE(S) AND COMPLIANT WITH ALL LAWS AND REGULATIONS APPLICABLE THERETO. TO THE EXTENT PERMITTED BY THE APPLICABLE LAW, DOW CORNING DISCLAIMS ALL LIABILITY WHATSOEVER, HOWSOEVER ARISING FROM OR IN CONNECTION WITH THE INFORMATION INCLUDING ANY LIABILITY FOR INCIDENTAL, INDIRECT, CONSEQUENTIAL AND SPECIAL DAMAGES.