

# **Regulatory Data Sheet**

# **DOWSIL™ EL-8048 ID Silicone Organic Blend**

Information provided in this Regulatory Data Sheet (RDS) does not indicate Dow product availability in all countries aligned with the below regulations. Please contact Dow to confirm availability of product in specific countries.

# **Global Chemical Inventory Compliance**

Country	Inventory	Status
Australia	AIIC	The product contains an intentional component that is subject to a restriction. Production and/or use is limited by the conditions of the restriction.  The product contains one or more substances that are subject to a specific information requirement by the Australian Industrial Chemicals Introduction Scheme (AICIS).
Canada	DSL	All substances contained in this product are listed on the Canadian Domestic Substances List (DSL) or are not required to be listed.
China	IECSC	All intentional components are listed on the inventory, are exempt, or are supplier certified.
Japan	ENCS	The product is used in a food, drug or cosmetic application and is subject to the applicable regulation.  The product may only be used in the exempt application.
Korea	KECI	All intentional components are listed on the inventory, are exempt, or are supplier certified.
New Zealand	NZIoC	Not assessed
Philippines	PICCS	All intentional components are listed on the inventory, are exempt, or are supplier certified.
Switzerland	EINECS	This product contains notifiable chemical substance(s) not on the EINECS Inventory. It may be used for research and development purposes only, and only under the supervision of a technically qualified individual. All persons engaged in research and development with this product must be informed of the hazard information in this Safety Data Sheet (SDS).
Taiwan	TCSI	All intentional components are either listed on the Inventory or exempted by regulations, or certified by venders of their supply chemicals.
United States of America (USA)	TSCA	The product is used in a food, drug or cosmetic application and is subject to the applicable regulation. The product may only be used in the exempt

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	l application.

# **Country/Area Additional Chemical Control Law Information**

Country/Area	Regulatory Reference	Details
EEA Countries, Switzerland	REACh Regulation (EC) No 1907/2006 Annex XVII	Please search https://www.dow.com/en-us/support/sds-finder.htm for the country Safety Data Sheet (SDS). If a SDS is not available, you may contact Customer Information Group at https://www.dow.com/en-us/contact-us.html to confirm product availability in this country and request a SDS.
Turkey	KKDIK Annex 17	Please search https://www.dow.com/en-us/support/sds-finder.htm for the country Safety Data Sheet (SDS). If a SDS is not available, you may contact Customer Information Group at https://www.dow.com/en-us/contact-us.html to confirm product availability in this country and request a SDS.

## **REACH**

REACH requires the registration of substances when they are manufactured or imported into the European Economic Area (EEA) at a volume of one metric ton or more per annum per legal entity. We hereby confirm that every REACH relevant substance in the composition of the above Dow product(s), made available on the EEA Market by Dow, has been accordingly covered under REACH, either via own registration or supplier coverage for the relevant tonnage band, and is therefore compliant with the REACH regulation (EC) N° 1907/2006 as per the official ECHA list published on the ECHA website https://echa.europa.eu/information-on-chemicals/registered-substances. The above statement is only valid for volumes imported into or manufactured within the EEA by Dow and placed on the market within the EEA. For customers based outside the EEA importing Dow products or products containing Dow products into the EEA, please note that these imports are not covered under the EEA Dow Legal Entity(ies) registrations. It is the obligation of the importer to ensure REACH compliance unless an agreement is in place that allows the importing non-EEA company's volumes to be covered under the Dow Only Representative Trustee model, which covers volumes of indirectly imported Dow products under the existing Dow registrations. The possibility of providing a Dow Only Representative Trustee coverage needs to be evaluated for each REACH relevant substance. For information on our products and REACH, visit the Dow REACH page https://reach.dow.com/en-us.

## **REACH Substances of Very High Concern (SVHC)**

For information on our products and the European Union regulation for Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), visit the Dow REACH page https://reach.dow.com/en-us/silicone-info. If any Substances of Very High Concern (SVHC) listed on the ECHA candidate list are above 0.1% they will appear in Section 15 of the European SDS.

## **Dietary Laws**



## Halal

This product does not contain ethanol, natural L-cysteine extracted from hair or feathers; animal fats and/or animal extracts; bloods of any origins; blood plasma; pork; and/or other meat by-products. Additionally, none of the components listed above are known by us to be present as impurities or by-products in any of the ingredients used to make this Product. Finally, ethanol is not used as a processing aid nor is it believed to be present as an impurity or by-product in this Product.

#### Kosher

This product is not Kosher certified.

# **Hazard Information Reporting (RTK)**

# California Prop. 65

This product contains a chemical that is at or below California Propositions 65's "safe harbor level" as determined via a risk assessment. Therefore, the chemical is not required to be listed as a Prop 65 chemical on the SDS or label.

#### Irradiation

#### <u>Irradiation</u>

This product does not contain material that has been irradiated nor has it been manufactured at any stage with irradiation.

# **Metal Regulations**

# Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act)

The Product is not intentionally formulated with tantalum, tin, tungsten or gold, nor are we aware that the Product contains tantalum, tin, tungsten or gold. However, we do not specifically analyze for the presence of these substances; therefore, we cannot guarantee the absence or level of these substances to any specific limit or threshold value.

# **Coalition of Northeastern Governors (CONEG)**

The following substances – cadmium, chromium VI, lead, or mercury, are not intentionally added to this product. Heavy metals are not expected to be present unless at trace levels as unknown impurities from the raw materials. This information is based upon our theoretical composition, data from our raw material manufacturers, and knowledge of our manufacturing process. Please note that we do not test our finished product for the presence of heavy metals. Coalition of Northeastern Governors (CONEG) legislation applies to the finished article.

# EU 94/62/EC - Packaging and Packaging Waste

Dow does not routinely analyze for additional materials that are not listed in the MSDS or Sales Specification. Specifically, while we have not analyzed for heavy metals referenced in EU Directive



94/62/EC (Cadmium, Hexavalent Chromium, Lead, Mercury), they are not known to be present in this product.

# Origin

# **Genetically Modified Organisms (GMO)**

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO).

# **Animal Derived Components (BSE/TSE)**

To the best of our knowledge, this product is not manufactured or formulated with ingredients of animal origin.

## Palm Oil

Based on process knowledge and based on statements from our vendors, the Product above is not expected to contain palm oil and its derivatives.

#### **Origin**

The Product is made from solely synthetic sources.

#### **Preservative**

## **Preservatives**

No preservative is intentionally added to this product.

# **Volatile Organic Compound**

#### **Volatile Organic Compounds (VOC)**

For VOC information, please consult your local EHS contact.

# **General/Global Regulations**

## **Allergens**

To the best of our knowledge, this product does not contain any of the 26 allergen ingredients as defined in the Cosmetics Products Regulation (EC) 1223/2009. To the best of our knowledge, there are no substances present in the Product that are listed in Annex II of Regulation (EU) 1169/2011 of the European Parliament and of the Council: cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains), crustraceans, eggs, fish, peanuts, soybeans, milk (including lactose), nuts (i.e. Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Caryaillinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut(Macadamia ternifolia)), celery, mustard, sesame seeds, sulphur dioxide, sulphites, lupin or molluscs and products



thereof. We are unaware of any potential sources for the introduction of any substances of concern from the manufacturing and packaging processes, nor from the packaging components themselves. We do not specifically analyze for the presence of these substances. Therefore, we cannot guarantee the level of these substances to any specific limit or threshold value.

# CMR

No substances greater than 0.1% classified as Carcinogenic, Mutagenic or toxic for Reproduction (CMR), of Categories 1A, 1B or 2 under Annex VI of Regulation (EC) N°1272/2008 are present in the product.

# **Endocrine Disruptors Statement**

To the best of our knowledge, this product does not contain any potential endocrine disruptors.

# Recommendation 2011/696/EU on the definition of nanomaterial

To be best of our current knowledge, we hereby confirm that this product does not meet the definition of nanomaterial as provided in the Commission Recommendation 2011/696/EU.

## **Belgium**

We understand the Belgian Royal Decree of 27 May 2014 concerning the placing on the market of substances produced in nanoparticular state, to define nanoparticles in accordance with the European Commission Recommendation 2011/696/EU, being however limited to (i) mixtures which are intentionally manufactured to contain nanoparticles where those nanoparticles are not linked or bound within those mixtures, and (ii) substances which are intentionally manufactured as nanoparticles. Moreover, our interpretation is that the Belgium Decree does not apply to (i) biocides, (ii) medicinal products for human or veterinary use, (iii) (products intended to come into contact with) foodstuff, (iv) animal feed or (v) technological aids or other products that may be used for processing ingredients of agricultural origin, and (vi) cosmetic products. To be best of our current knowledge, we hereby confirm that this product does not meet the aforementioned definition.

#### France

We understand the French Decree 2012-232 related to the annual declaration of nanomaterials in France and accompanying Ministerial Order of August 6, 2012 to define nanoparticles in accordance with the European Commission Recommendation 2011/696/EU, being however limited to (i) mixtures which are intentionally manufactured to contain nanoparticles where those nanoparticles are not linked or bound within those mixtures, and (ii) substances which are intentionally manufactured as nanoparticles. To be best of our current knowledge, we hereby confirm that this product does not meet the aforementioned definition.

## EU Cosmetics Regulation 1223/2009/EC

This product does not meet the definition of a nanomaterial as listed in Article 2(k) of the EU Cosmetic Regulation. This product would not trigger the notification requirements of Article 16 or the need for any further safety assessment that is required for a cosmetic product due to the presence of nanomaterials.



## **Residual Solvents**

None of the Class 1 and Class 2 Residual Solvents specified in USP General Chapter <467> effective on 1 JUL 2008 are used in the manufacture of this product.

# TSCA 12b

We have reviewed the composition of the Product for the presence of TSCA 12b listed substances. Based on that review, the Product does not contain chemical components subject to TSCA section 12(b) export notification.

# **Substances and Compounds**

The following substances are not expected to be present in this Product. We may not specifically analyze for the presence of these substances in the Product. Therefore, we cannot guarantee the absence or level of these substances to any specific limit or threshold value:

Alkylphenols and Alkylphenol Ethoxylates Aluminum (Al) or aluminum compounds Antimony (Sb) or antimony compounds Aromatic Amines Arsenic (As) or arsenic compounds Asbestos

Azo compounds

Barium (Ba) or barium compounds

Beryllium (Be) or beryllium compounds

Bismuth (Bi) or bismuth compounds

Bisphenol A

Boron (B) or boron compounds

Cadmium (Cd) or cadmium compounds

Ceramic fibers

Cerium/Cerium Compounds

Chlorofluorocarbons

Chromium (Cr) or chromium compounds

Cobalt (Co) or cobalt compounds

Copper (Cu) or copper compounds

**Dimethyl Fumarate** 

Fluorotelomer

Formaldehvde

Glycol Ethers classified as Reprotox 1A or 1B

Gold or Gold compounds

Halogenated Flame Retardants

Hydrochlorofluorocarbons (HCFC)

Hydrofluorocarbons (HCF)

Natural Rubber Latex (NRL)

Lead/Lead Compounds

Lithium (Li) or lithium compounds

Magnesium/Magnesium Compounds

Manganese (Mn) or manganese compounds



Mercury (Hg) or mercury compounds

Nickel (Ni) or nickel compounds

**Nitrosamines** 

Ozone Depleting Substances

Perfluorooctane sulfonate (PFOS)

Perfluorooctanoic acid (PFOA)

Phenol

Phthalates - as listed on the EPA Phthalates Action Plan

Colorants or pigments

Polyaromatic Hydrocarbons

Polybrominated Biphenyls (PBB)

Polybrominated Diphenyl ether (PBDE)

Polychlorinated Biphenyls (PCB)

Polyvinyl Chloride (PVC)

Radioactive substances

Selenium (Se) or selenium compounds

Silver (Ag) or silver compounds

Strontium/Strontium Compounds

Tantulum/Tantalum Compounds

Tellurium (Te) or tellurium compounds

Thallium (TI) or thallium compounds

Tin/Tin compounds/Organic Tin

Tungsten (W) or tungsten compounds

Vanadium/Vanadium Compounds

Zinc (Zn) or zinc compounds

Zirconium/Zirconium Compounds

# **Product Specification**

For product specifications, please request a Sales Spec document for this product from The Dow Customer Information Group at http://www.dow.com/en-us/contact-us-cig.

#### **Composition Statement**

For information on the components of our product and their concentration, please refer to the Safety Data Sheet (SDS) and the Sales Specification. Any hazardous constituents above regulatory disclosure cut-off limits determined according to their regional and/or specific GHS classification(s) will appear in the ingredients section of the SDS. In addition, consult the Hazardous Decomposition Products section for further information. You can search https://www.dow.com/en-us/support/sds-finder.html for an available SDS.

# **Responsible Care**

Dow complies with the American Chemistry Council's Responsible Care® guiding principles, codes, and management system requirements. Dow has recommitted its support for Responsible Care on a global scale by signing the Responsible Care Global Charter under the auspices of the International Council of Chemical Associations (ICCA). Dow has also endorsed the ICCA's Global Product Strategy, an effort by the global chemical industry to further improve its product stewardship efforts. Our EH&S management



system is audited regularly to ensure compliance with all applicable governmental requirements, Responsible Care, and internal Dow requirements.

Dow has adopted what we call our "2025 Sustainability Goals" -- ambitious performance improvement goals with a broad external focus: strengthening our relationships with the communities where we operate, continuing to improve our product stewardship and innovation, and reducing our global footprint. In support of these goals, Dow is constantly working to improve our performance through focused EH&S programs such as the Waste Reduction Always Pays (WRAP) program. More information can be found by visiting https://www.dow.com/en-us.html.

#### **Product Stewardship**

Dow has a fundamental concern for all who make, distribute, and use its products, and for the environment in which we live. This concern is the basis for our product stewardship philosophy by which we assess the safety, health, and environmental information on our products and then take appropriate steps to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Dow products - from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

#### **Customer Notice**

Dow strongly encourages its customers to review both their manufacturing processes and their applications of Dow products from the standpoint of human health and environmental quality to ensure that Dow products are not used in ways for which they are not intended or tested. Dow personnel are available to answer your questions and to provide reasonable technical support. Dow product literature, including safety data sheets, should be consulted prior to use of Dow products. Current safety data sheets are available from Dow.

#### **Medical Applications Policy**

NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS: Dow does not support or intend for its products to be used in: a. long-term or permanent contact with internal bodily fluids or tissues. "Long-term" is contact which exceeds 29 calendar days; b. use in cardiac prosthetic devices regardless of the length of time involved ("cardiac prosthetic devices" include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypassassisted devices);

- c. use as a critical component in medical devices that support or sustain human life; or
- d. use specifically by pregnant women or in applications designed specifically to promote or interfere with human reproduction.

e. use as an ingredient of a pharmaceutical injectable application.

Dow requests that customers considering use of Dow products in medical applications notify Dow so that appropriate assessments may be conducted. Dow does not endorse or claim suitability of its products for specific medical applications. It is the responsibility of the medical device or pharmaceutical manufacturer to determine that the Dow product is safe, lawful, and technically suitable for the intended use. DOW MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY DOW PRODUCT FOR USE IN MEDICAL APPLICATIONS.

#### **Tobacco and Marijuana Policy**

Dow does not support or intend for its products to be used, directly or indirectly, in the production of tobacco, the manufacture of tobacco products, the manufacture and use of electronic cigarettes/vaping, the production of marijuana, or the manufacture of marijuana products intended for human consumption, where the Dow product (or its residues) may be present in the finished product or be alleged to facilitate the delivery of nicotine, other tobacco components, marijuana, or marijuana components.

# **Harmful Applications Policy**

Dow does not intend for its products to be used in applications specifically intended to harm humans.

NOTICE: No freedom from infringement of any patent owned by Dow or others is to be inferred. Because use conditions and applicable laws may differ from one location to another and may change with time, the Customer is responsible for determining whether products and the information in this document are appropriate for the Customer's use and for ensuring that the Customer's workplace and disposal practices are in compliance with applicable laws and other governmental enactments. Dow assumes no obligation or liability for the information in this document. NO WARRANTIES ARE GIVEN, ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED.

For additional information, not covered by the content of this document, contact us via our web site http://www.dow.com/products\_services/.



