



Regulatory Data Sheet

ENGAGE™ 8480K Health+™ Polyolefin Elastomer

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	All substances contained in this product are listed on the Australian Inventory of Industrial Chemicals, or are not required to be listed.
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	All intentional components are listed on the inventory, are exempt, or are supplier certified.
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	The components of this product are on the EINECS inventory or are exempt from inventory requirements.
Taiwan	TCSI	Not assessed
United States of America (USA)	TSCA	All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

REACH

For information on Dow and the European Union regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), visit our website, <https://reach.dow.com/en-us>. This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet that would require reporting under this regulation. Current information can be found at the ECHA website. <https://echa.europa.eu/candidate-list-table>. Please contact Dow's Customer Information Group for more information (<http://www.Dow.com/en-us/contact-us-cig>).

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Food Contact Regulations

The following status applies when used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications.

Regulation	Statement
21CFR177.1520 Olefin polymers	The composition of this product complies with this regulation with limitation. Paragraph (c)3.2c Use is limited to Food Types I through IX listed Table 1, under conditions of use C through H identified in Table 2 per 176.170(c).
Canadian Food and Drug Regulations, Division 23 Food Packaging Materials	The composition of this product has not been assessed for this regulation.
Indian Standards for use in contact with foodstuff, pharmaceutical, or drinking water applications	The composition of this product has not been assessed for this regulation.
GB 31603-2015 Food Safety National Standard for Good Manufacture Practise of Food Contact Materials and Articles	The composition of this product complies with this regulation. Please contact Dow at FGLREGL@dow.com if you require a detailed food contact letter.
GB 4806.1-2016 Food Safety National Standard for General Safety Requirements for Food-Contact Materials and Articles	The composition of this product complies with this regulation.
GB 4806.6-2016 Food Safety National Standard for Food-contact Use Plastic Resins	The composition of this product complies with this regulation.
GB 9685-2016 Food Safety National Standard of Use of Additives for Food contact Materials and Articles	The composition of this product complies with this regulation. Please contact Dow at FGLREGL@dow.com if you require a detailed food contact letter.
Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) voluntary standard for food contact substances and polymers	This product is not registered.
MERCOSUR - Resolución GMC No. 02/2012 - Monomers, other Starting Substances, and authorized Polymers for Plastic Packaging and Equipment in Food Contact	The composition of this product complies with this regulation.
MERCOSUR - Resolución GMC No. 39/2019 - Additives for Plastic Materials and Polymeric Coatings in Food Contact	The composition of this product complies with this regulation.
MERCOSUR - Resolución GMC No. 56/1992 - General Provisions for Plastic Packaging and Equipment in Food Contact	The composition of this product complies with this regulation.
ANVISA - RDC Resolução No. 052/2010 - Dyes in Plastic Packaging and Equipments intended to come into Contact with Food	The composition of this product complies with this regulation.
ANVISA - RDC Resolução No. 056/2012 - Monomers, other Starting Substances, and	The composition of this product complies with this regulation.



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authorized Polymers for Plastic Packaging and Equipment in Food Contact	
ANVISA - Resolução No. 105/1999 - General Provisions for Plastic Packaging and Equipments to come into Contact with Food	The composition of this product complies with this regulation.
ANVISA - RDC Resolução No. 326/2019 - Additives intended to the production of Plastic Materials and Polymeric Coatings to come into Contact Food	The composition of this product complies with this regulation.
INVIMA - Resolución No. 4143/2012 - Plastic and Elastomeric Materials, Objects, Packaging, and Equipments (and their additives) intended to come into Contact with Food and Beverages for human consumption	The composition of this product has not been assessed for this regulation.

Please contact Dow's Customer Information Group if you require further information (<https://www.dow.com/en-us/contact-us.html>).

It remains the responsibility of the food producer to determine the suitability of the product for the end use and to ensure the legal and regulatory compliance of the product as incorporated into foods. It remains the responsibility of the manufacturer of the material/article which in its finished state is intended for food contact applications to determine the suitability of the product for the end use and to ensure the legal and regulatory compliance of the product as incorporated in the material/article intended for food contact applications, including SMLs, QM and other restrictions/limits under the applicable law/regulations.

Pharmaceutical Regulations

U.S. Food & Drug Administration (FDA) Drug Master File

This product is listed under FDA Drug Master File 4251.

U.S. Pharmacopoeia (USP) <661.1> Plastic Materials Of Construction

The composition of this product complies with this regulation.

U.S. Pharmacopoeia (USP) - Class VI

The composition of this product complies with this regulation.

Dietary Laws

Halal

This product does not contain any substances of animal origin. To the best of our knowledge this product can be used with halal products without compromising the halal status of the products.



Kosher

This product does not contain any non-kosher substances. To the best of our knowledge, this product can be used with kosher products without compromising the status of the products.

Child Safety Regulations

Consumer Product Safety Improvement Act of 2008 (CPSIA)

This product is not manufactured or formulated with lead, di-(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). To the best of our knowledge, it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.

Toy Safety - ASTM F963 / EN 71-3

This product is not formulated with antimony, arsenic, barium, boron, cadmium, chromium, cobalt, copper, mercury, lead, nickel, selenium, strontium or tin. To the best of our knowledge, it does not contain these substances above the limits set in ASTM F 963-11, Section 4.3.5.2. This product complies with the requirements of EN 71 Safety of Toys - Part 3, Migration of Certain Elements.

Environment - Air

Clean Air Act

This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

Hazard Information Reporting (RTK)

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Metal Regulations

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

This product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; however, we do not analyze for these specific substances or compounds.

- Columbite-Tantalite – refined into Tantalum (Ta) (CAS # 7440-25-7)
- Cassiterite – refined into Tin (Sn) (CAS # 7440-31-5)
- Wolframite – refined into Tungsten (W) (CAS # 7440-33-7)
- Gold (Au) (CAS # 7440-57-5)

For more information please visit Dow's Corporate Website - <https://corporate.dow.com/en-us/about/codes-of-conduct>



EU 94/62/EC - Packaging and Packaging Waste

This product conforms to the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

Coalition of Northeastern Governors (CONEG)

This product conforms to the Coalition of Northeastern Governors (CONEG) Toxic in Packaging Legislation. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

Mineral Oil**Mineral Oil Aromatic Hydrocarbons / Mineral Oil Saturated Hydrocarbons**

This product is not intentionally formulated with Mineral Oil Aromatic Hydrocarbons (MOAH) or Mineral Oil Saturated Hydrocarbons (MOSH); however, trace amounts (ppm) of food grade, White Mineral Oil (MOSH) in compliance with Commission Regulation (EU) No 10/2011 and U.S. FDA food contact requirements may be present.

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

This product does not contain substances of animal origin, and, to the best of our knowledge, does not come into contact with substances of animal origin during its manufacturing process.

Palm Oil Derived Components

Palm oil, as such, is not used in the manufacturing of this product; however, palm oil derivatives are used in the manufacturing of one or more raw materials utilized in the production of this product. These palm oil derivatives are only purchased from suppliers which are members of the "Roundtable on Sustainable Palm Oil" (RSPO).

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). This is based on information from our additive suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

Plant Derived Components

This product may contain one or more substances(s) synthesized from plant extracts, i.e. hydrolysis of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.



Waste Regulations

EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

EU Directive 2012/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

General/Global Regulations

Food Allergens

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish (mollusks), crustaceans, tree nuts, mustard, celery, sesame, sunflowers, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. No sulfates, sulfites, or sulfur dioxide are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

Canadian Environmental Protection Act - Challenge Substances

This product is not intentionally manufactured or formulated with the Batch Lists of Canadian Environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this document. However, we do not analyze for these specific substances.
(<http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php>)

EU Directive 2011/65/EU (RoHS)

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive) (RoHS 3). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

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:

1,4-Dioxane
2-Isopropylthioxantone (ITX)
Acrylamide
Adipates
Alkyl phenols



Alkylphenol ethoxylates
Antimony (Sb) or antimony compounds
Aromatic Amines
Arsenic (As) or arsenic compounds
Asbestos
Azo compounds
Benzophenones
Beryllium (Be) or beryllium compounds
Biocides
Bis(2-ethylhexyl) adipate (DEHA)
Bisphenol A
Bisphenol A-diglycidylether (BADGE)
Bisphenol B (BPB) (77-40-7)
Bisphenol C (BPC) CAS# 79-97-0
Bisphenol E (BPE) (2081-08-5)
Bisphenol F
Bisphenol F diglycidyl ether (BFDGE)
Bisphenol S (BPS) (CAS No. 80-09-1)
Bisphenol Z (BPZ)(843-55-0)
Butylated Hydroxy Anisole (BHA)
Butylated Hydroxy Toluene (BHT)
Cadmium (Cd) or cadmium compounds
Chlorinated paraffins
Chlorofluorocarbons (CFCs) or Hydrochlorofluorocarbons (HCFCs)
Colophonium / Gum rosin / Rosin
Colorants or pigments
Copper (Cu) or copper compounds
Dimethyl Fumarate
Dioxins
Dry Natural Rubber (DNR)
Endocrine Disrupting Substances
Fiberglass
Flavorings
Fluorescent whitening agents
Fluorotelomer
Formaldehyde
Fragrances
Fungicides
Furans
Halogenated Flame Retardants
Hexachlorobenzene
Isocyanates
Jatropha Plant (Derivatives or parts)
Latex
Lead/Lead Compounds
Melamine
Mercury (Hg) or mercury compounds
Nanomaterials
Natural Rubber Latex (NRL)



Nickel (Ni) or nickel compounds
Nonylphenol
Nonylphenol ethoxylates
Novolac Glycidyl Ether (NOGE)
Organic nitro- or nitroso- containing substances
Organo-Tin Compounds
Ozone Depleting Substances
Parabens
Pentachlorophenol
Perchlorates
Perfluoroalkyls (PFAS)
Perfluorooctane sulfonate (PFOS)
Perfluorooctanoic acid (PFOA)
Pesticides
Phthalate esters
Phthalates
Plasticizers
Polybrominated Biphenyls (PBB)
Polybrominated Diphenyl ether (PBDE)
Polybrominated Terphenyls (PBT)
Polychlorinated and Polybrominated Naphthalenes
Polychlorinated Biphenyls (PCB)
Polychlorinated Terphenyls (PCT)
Polycyclic Aromatic Hydrocarbons (PAHs)
Polyfluoroalkyls (PFAS)
Polyvinyl Chloride (PVC)
Polyvinylidenechloride (PVDC)
Radioactive substances
Recycled materials
Silicone / Surface active substances
Silver (Ag) or silver compounds
Styrene
Synthetic Latex
Tertiary butylhydroquinone (TBHQ)
Triclosan
Tris(2-chloroethyl)phosphate (TCEP)
Tris(nonylphenyl)phosphite (TNPP)
Vinyl chloride (Chloroethylene)
Xylene
Zinc (Zn) or zinc 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 bypass-assisted 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.

Disclaimer

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, Customer is responsible for determining whether products and the information in this document are appropriate for Customer's use and for ensuring that Customer's workplace and disposal practices are in compliance with applicable laws and other government enactments. The product shown in this literature may not be available for sale and/or available in all geographies where Dow is represented. The claims made may not have been approved for use in all countries. Dow assumes no obligation or liability for the information in this document. References to "Dow" or the "Company" mean the Dow legal entity selling the products to Customer unless otherwise expressly noted. NO WARRANTIES ARE GIVEN; ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED. NO WARRANTIES ARE GIVEN; ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED.

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