



Regulatory Data Sheet

4011 Prism® Medical Device Instant Adhesive

Product ID 142059

Page 1 of 5

142059 V001.7

Revision: 2024-FEB-01

printing date: 2024-MAY-16

Replaces version from: 2023-JUN-22

GENERAL INFORMATION

The safety and regulatory data provided in this RDS is based on our current knowledge and on supplier information that we have not independently verified. Due to the various possible applications and the application and working conditions beyond our control, this RDS may not be adequate to satisfy any requirements you may have under relevant laws and regulations applicable. Hence, the data provided herein does not release you from conducting your own risk assessment prior to any use in your production or before application of Henkel product. In particular, we do not assume any liability for the suitability of our products for the relevant production processes under the specific working conditions and the intended processing purposes and results. Henkel latest updated product information, including but not limited to technical and safety data sheets, should be consulted prior to use of Henkel products.

Please be informed that we do not check any import/export requirements applicable to you under the conditions of the local legal systems. The responsibility for the legality of imports and exports of our products lies solely with the respective importer or exporter - Henkel as a manufacturing company does not know the individual circumstances of our customer's imports and exports and is therefore not in a position to assess any regulatory requirements including but not limited to import restrictions and/or corresponding obligations such as notification requirements et.al.

Henkel cannot exclude that certain substance(s) may be present as adventitious trace impurities (not intentionally added to the product). Such analyses for trace impurities in the products are not conducted as part of routine Henkel procedures.

The information in this document applies to the best of our knowledge regarding the product as of the date it has left our premises. Henkel is not obliged to update any of this information.

PROHIBITION AND RESTRICTIONS

EU REACH Annex XVII

To the best of our knowledge, this product does not contain substances which are listed in the current Annex XVII to the REACH Regulation (EC) No 1907/2006 at 0,1 weight% or higher.

EU REACH Annex XIV

To the best of our knowledge, this product does not contain substances which are listed in the current version of Annex XIV (substances subject to Authorisation) at a percentage of 0,1 weight% or higher.

EU REACH SVHC

To the best of our knowledge, this product does not contain substances which are listed in the current version of the candidate list of Substances of Very High Concern (SVHC) at a percentage of 0,1 weight% or higher.

GLOBAL INVENTORY STATUS

Country	Inventory	Inventory Status
USA	TSCA 8(b)	All components are listed as active or are exempt from listing on the Toxic Substances Control Act (TSCA) inventory.
USA		Some substances on the US Chemical Inventory may be subject to a rule or order promulgated by EPA under TSCA. These substances could have restrictions associated with manufacturing, import, processing, use or disposal. To determine if a substance in this product is subject to a TSCA rule or order, please see the US Safety Data Sheet or contact Henkel Product Safety & Regulatory Affairs.
Canada	DSL	Contains one or more components listed on the Non-Domestic Substances List. All other components are listed on or are exempt from listing on the Domestic Substances List. Components listed on the NDSL must be tracked by all Canadian Importers of Record as required by Environment Canada. They may be imported into Canada in limited quantities. Please contact Regulatory Affairs for additional details.
Chile	SQI	Please contact your local Henkel representative.
Colombia	INSQUI	Please contact your local Henkel representative.
Europe	REACH	Please contact your local Henkel representative.
Switzerland	CHEM-O	Please contact your local Henkel representative.
United Kingdom	UK REACH	Please contact your local Henkel representative.
Turkey	KKDIK	Please contact your local Henkel representative.
Australia	AiIC	All components are listed or are exempt from listing on the Australian Inventory of Industrial Chemicals or Introduced under AICIS.
China	IECSC	All components are listed or are exempt from listing on the Inventory of Existing Chemical Substances in China (IECSC)
Japan	ENCS	All components are listed or are exempt from listing on the Japanese List of Existing and New Chemical Substances (ENCS)
Japan	ISHL	All components are listed or are exempt from listing regarding the Japanese Industrial Safety and Health Law (ISHL)
South Korea	KECI	All components are listed or are exempt from listing on the Korean Existing Chemicals Inventory (KECI). Please contact your local Henkel representative.
New Zealand	NZIOC	All components are listed or are exempt from listing on the New Zealand Inventory of Chemicals (NZIOC)
Philippines	PICCS	All components are listed or are exempt from listing on the Philippines Inventory of Chemicals and Chemical Substances (PICCS)
Taiwan	TCSI	All components are listed or are exempt from listing on the Taiwan Existing Chemicals Inventory (TCSI)

Country	Inventory	Inventory Status
		Please contact your local Henkel representative.

SUBSTANCES OF CONCERN

To the best of our knowledge, after plausibility check of the above referenced product(s) formulation, on the date the products has left the premises, the presence of substances is as follows:

(Note: The below list contains both single substances and substance groups. If "Yes" is indicated for a substance group, it means that one or multiple substances of the group is/are present)

Substances	Threshold Limit	Present
Perfluorooctanoic acid (PFOA) and salts	25 ppb	No
Dimethyl fumarate	100 ppb	No
Polycyclic aromatic hydrocarbons (PAH)	1 ppm	No
Hexachlorobenzene	10 ppm	No
Perfluorooctane sulfonates (PFOS) and salts	10 ppm	No
Polychlorinated naphthalenes (PCNs)	10 ppm	No
Polychlorinated Biphenyls (PCBs)	50 ppm	No
Polychlorinated Terphenyls (PCTs)	50 ppm	No
Hexabromocyclododecane	100 ppm	No
Asbestos	0,1 % (w/w)	No
Azo colorants forming certain aromatic amines	0,1 % (w/w)	No
Benzene	0,1 % (w/w)	No
Benzotriazolyl-4,6-di-tert-butylphenol	0,1 % (w/w)	No
Chlorinated phosphate esters (TDCPP, TCEP, TCPP)	0,1 % (w/w)	No
Formaldehyde	0,1 % (w/w)	No
Organotin compounds (DBTs, DOTs, TBTs, TPTs)	0,1 % (w/w)	No
Ozone Depleting Substances (ODSs)	0,1 % (w/w)	No
Phthalates (DEHP, BBP, DBP, DIBP)	0,1 % (w/w)	No
Radioactive substances	0,1 % (w/w)	No
Short Chain Chlorinated Paraffins (C10-13)	0,1 % (w/w)	No
Specified brominated flame retardants (PBBs, PBDEs)	0,1 % (w/w)	No

DISCLAIMER

Henkel does not give any warranty nor assume any responsibility with regard to the correctness, completeness and validity of the information provided in this RDS. Any liability resulting from the information contained in this RDS and any other written or oral advice given for this product is expressly excluded. This limitation of liability does not apply in case of our intent or gross negligence, in case of death, injury or detriment of health due to our default and an infringement of essential contractual obligations, if any, to HENKEL's default. However, HENKEL's liability for an infringement of essential contractual obligations, if any, shall be limited to reimbursement of foreseeable, contractually typical damages, unless we are liable due to intent or gross negligence, death, injury or detriment of health, or pursuant to the applicable liability laws.