



## ***Regulatory Data Sheet***

LOCTITE® 4601™ INSTANT ADHESIVE PRISM® MEDICAL  
DEVICE ADHESIVE

Product ID 229810

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229810 V001.4

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### **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.

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## PROHIBITION AND RESTRICTIONS

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### EU REACH Annex XVII

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To the best of our knowledge, this product contains the substance(s) detailed below, as listed in the current Annex XVII to the REACH Regulation (EC) No 1907/2006 at 0,1 weight% or higher. Please check the details and applicability of the restriction in the provided entry.

**Contains**

CAS: 119-47-1      Bis(2-hydroxy-3-tert-butyl-5-methylphenyl)methane      Entry: 30

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### EU REACH Annex XIV

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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.

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### EU REACH SVHC

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To the best of our knowledge, this product contains the substance(s) detailed below, as 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.

**Contains**

CAS: 119-47-1      Bis(2-hydroxy-3-tert-butyl-5-methylphenyl)methane

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**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       | All components are listed on or are exempt from listing on the Canadian Domestic Substances List.   |
| 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      | AIC       | 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).<br><br>Please contact your local Henkel representative.   |
| New Zealand    | NZIOC     | Please contact your local Henkel representative.  |
| 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)<br><br>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      |

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**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.