



## **Global Regulatory Service**

Hand in hand with our customers

English B-13

# Who we are

BYK is one of the leading suppliers in the field of additives. Our products improve, for example, the scratch resistance and gloss of surfaces or optimize manufacturing processes.

The coatings, printing inks and plastics industries are among the major customers of BYK additives. Yet it is also in the fields of oil and gas production, the manufacture of care products, the production of sealants and adhesives, and construction chemistry that BYK additives improve the product characteristics and manufacturing processes.

As a globally active specialty chemicals company, we have production sites in Germany, the Netherlands, the UK, the USA and China.

The company today employs around 2,000 staff worldwide and is part of the ALTANA Group.

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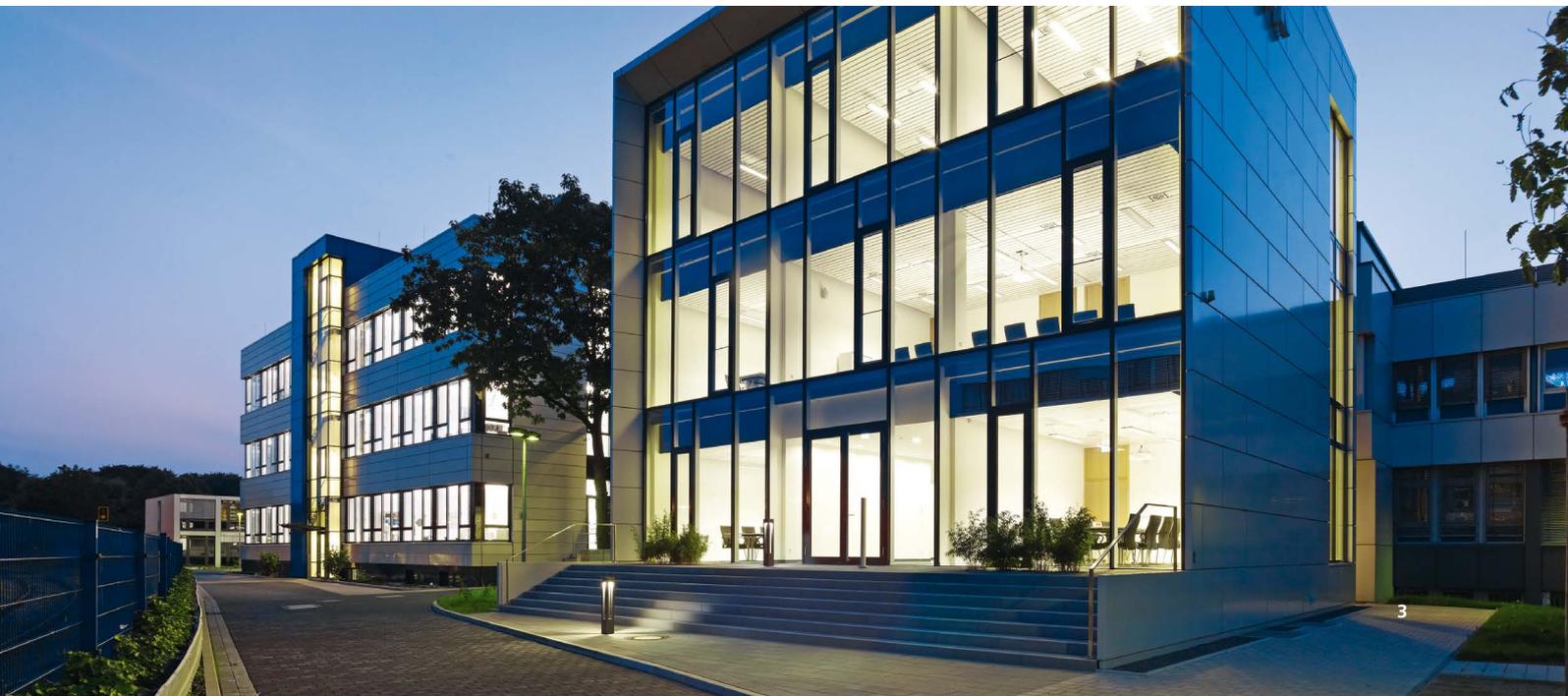
# Ensuring a competitive edge and minimizing risks

Any business wishing to be globally successful today needs not only to be fully aware of the laws and regulations operating in the various regions and countries but also comply with them. Particularly for companies within the chemicals industry, such regulatory compliance is extremely important. It creates competitive advantages: only a business processing materials that are proven not to pose any risks is on the safe side.

That is why we work hand in hand with our customers. We support them with our expertise and thereby ensure product safety. At the same time, we relieve them of complex, time-consuming activities.

Our customer-focused regulatory service enables us to make our extensive knowledge of the relevant regulatory provisions that apply to our sector globally available to you too. It gives you fast access to detailed and accurate information – precisely at the point you need it – be it for the initial stages of development, for making the final purchasing decision, or for documenting your formulations.

With this brochure, we offer you an overview of what you can expect from us in the matter of regulatory compliance. Because our years of experience working with our customers have taught us one thing very well: any product is only as good as the service accompanying it.



# Closeness

isn't purely geographical

The more the world grows closer together, the more standardized will the processes in companies become. Many of our customers produce the very same product at various sites in different regions of the world. To do this, they require the very same globally available additive. Thanks to our global regulatory service, you can assume that this product conforms to the applicable regional regulations anywhere in the world.

This is possible because BYK has brought together a highly qualified, international team involving proven specialists. They are the direct points of contact for our customers – for initial inquiries and for collaboration on existing projects alike.

Collectively, the Global Regulatory Service Team manages all aspects relating to product safety, product stewardship, and the registration of chemical substances. Some team members work locally at our regional sites; others coordinate the activities centrally at our main headquarters in Wesel. Thanks to close networking and intensive cooperation, our customers can be confident of receiving the same reliable service anywhere in the world.

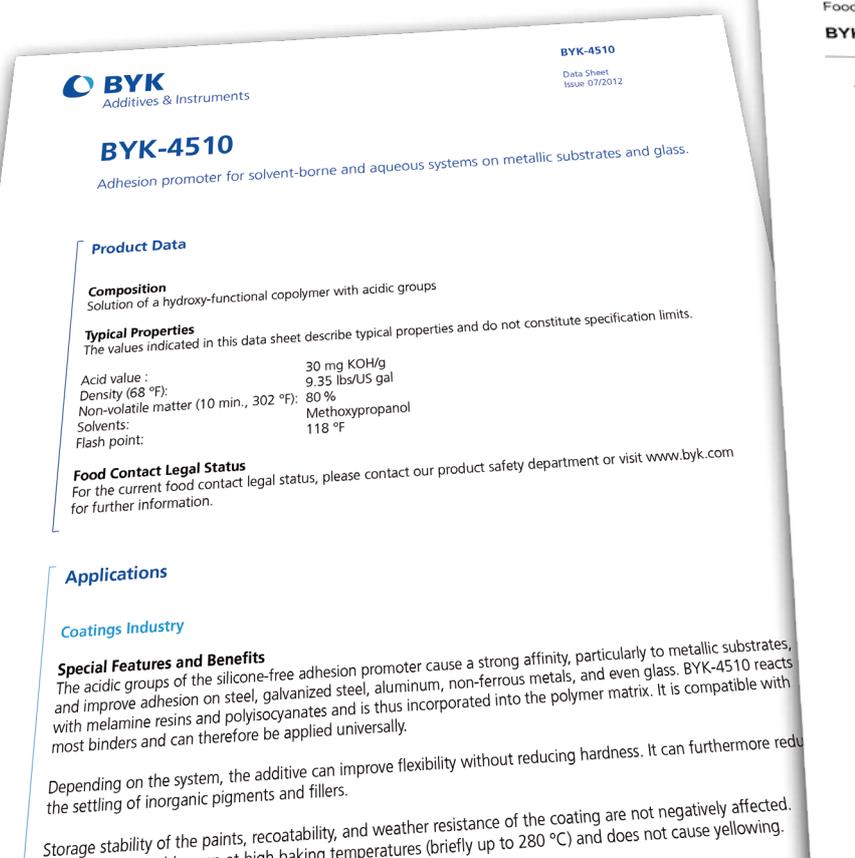
## Local specialists

Whether it's Europe, America or Asia, the local teams are not only available as a direct point of reference for our customers. The specialists are also in close contact with authorities, networks and associations. This enables them to recognize new developments as they start and to respond appropriately. Their duties include entering our products in the local chemical registers and data management in the national language.

## Product stewardship

BYK is committed to the concept of product stewardship. As part of our regulatory services, we provide the appropriate information in concentrated form, in a special data sheet called BRIEF – "BYK Regulatory Information Extensive Form". This contains all the relevant regulatory data worldwide, as well as further information on product safety.

The technical data sheet (TDS, left) and the data sheet on the subject of food contact (right)



▶ **Our aim:** one product, suitable for any region of the world.

## Global registration of substances

BYK reports and registers its products in accordance with the national, regional or industry-specific requirements concerned. These include national provisions such as the U.S. Toxic Substance Control Act (TSCA) and the Australian Inventory of Chemical Substances (AICS) or the European REACH register (for the Registration, Evaluation, Authorisation and Restriction of Chemicals).

## Special markets

We also keep information on special markets such as food contact, toy compatibility or decorative applications. In addition, we can supply data on product tests and recommendations for gas and oil production or other markets.

## Standardized data management

The Global Regulatory Service Team also manages the data resulting from registration and ensures that our customers have access, with our support, to all the information that is relevant to them. The basis for this is our central database. When dispatching our additives, for example, we use it to automatically generate country-specific safety data sheets, labels and dangerous goods indicators, which are tailored exactly to the product and the particular regional regulations.



Contact Regulatory Status Information

BYK®-4510  
Version 2.0

**BYK**  
Additives & Instruments

4/29/2016

### 1. Evaluation according to EU regulation

- 1.1. The active component of this product is manufactured using monomers which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table 1 of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (including its amendments: Regulation 1282/2011, Regulation 1163/2012, Regulation 202/2014, Regulation 2015/174). Restrictions apply.
- 1.2. The active component as such is not listed as a "polymeric additive" in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in compliance with this regulation. However, the product falls under the definition of polymer production aid (PPA) of the Regulation (EU) No 10/2011, if a technical effect is achieved only in the application process, and the product is neither intended to be present in the finished materials or articles nor does it have a physical or chemical effect in the final material or article. PPAs other than those listed in the Union list may be used to manufacture plastics, subject to national legislation. The final decision regarding the concerned use ("polymeric additive" or PPA) is depending on the use application and falls into the responsibility of the manufacturer of the final product.
- 1.3. All components of this product are conform to the compositional requirements of the German BfR-Recommendation XIV 'Plastic Dispersions' and XXXVI 'Paper and board in contact with food' (due to cross reference).
- 1.4. For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the CEPE 'Code of practice for food contact coatings', Edition 4, Version Feb. 2009 and in the Dutch Warenwet – Chapter X for coatings.
- 1.5. The product contains a significant amount of solvent. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.
- 1.6. BYK-Chemie GmbH has a certified Quality Management System according to ISO 9001:2008 and is therefore regarded to be in compliance with the requirements of Commission Regulation (EC) 2023/2006 regarding "Good Manufacturing Practice" (GMP) in the food packaging supply chain.
- 1.7. For impurities resulting from residual formulation aids and raw materials, Art. 3 of Framework Regulation (EC) 1935/2004 apply (see general remarks).

In summary, based on the product recipe, we can state that the components of the product are listed in European regulations for use in coatings with food contact. **However, final legal compliance needs to be verified by the producer of the final article under consideration of the final application and the conditions of use of the product.** Furthermore, we recommend migration testing to verify compliance.

### 2. Evaluation according to the Swiss Ordinance

The product is conform to the compositional requirements of the part for printing inks for packaging of (Annex 22 November 2005 last amended on 01 April 2013)

# Our expertise is multi-faceted

At BYK, the groundwork and support for the necessary regulatory expertise already starts with product development. A systematic sustainability analysis is part of our innovation process from a very early stage.

Our developers will examine whether the planned formulation meets the regulatory requirements for the application in question when it is still in the laboratory phase. If this is not the case, they will look for alternatives. This also applies if, say, health or environmental risks from the substances are to be anticipated.

Last but not least, we make use of our expertise that has accrued from our long-pursued Greenability strategy. It serves to support our customers with suitable additives in developing more eco-friendly products. Ultimately, our company's own objectives regarding climate protection and the reduction of CO<sub>2</sub> or VOCs (volatile organic compounds) help to minimize risks.

Newly developed products are immediately registered in all relevant national and international chemical registers, after the laboratory phase to ensure marketability where you need it, when you need it. We commit the suppliers of our raw materials to comply with our code of conduct and thus to comply with the Global Compact principles of the United Nations.



## **Informative and popular: BRIEF**

As part of our commitment to product stewardship, we provide users with the best possible support well after product rollout. Technical data sheets and safety data sheets, ready for use forms and other documents assist in this.

Our BRIEF documents are especially popular. We supply one for every additive and thus make our expertise available to our customers in a concentrated form. The documents can be downloaded from our website.

The BRIEF document contains all important data regarding product safety and compliance with the national or international legislation concerned. This includes the list of all registers and directories worldwide in which the product has been entered, as well as the corresponding directives. If regulations change or new ones are added, we update the BRIEF document accordingly.

For all questions pertaining to REACH as well as applications under REACH, the BRIEF document provides references to the appropriate special sections of the BYK website. It also explains whether potentially critical constituents such as VOCs or other substances are contained in the product and what are explicitly not contained. Anyone requiring additional information will find the contact details of the BRIEF team also included in the document.

**▶ Our operating principle:**  
sustainable product design from  
the outset.

**BRIEF** (BYK Regulatory Information - Extensive Form)

Product name: **BYK4510**

**1. Inventory status**

The components of the products are contained in the following inventories or exempt from listing:

Switzerland (EINECS)	yes
USA (TSCA)	yes
Canada (DSL)	yes
Japan (ENCS)	yes
Philippines (PICCS)	yes
China (IECSC)	yes
Australia (AICS)	yes
Korea	yes
New Zealand (NZIoC)	yes
Taiwan (ECSI)	yes

Please note that the current inventory<sup>y</sup> has been replaced by K-REACH.  
<sup>y</sup>For additional information, contact BRIEF.BYK@altana.com

**2. Information on REACH** (Registration, Evaluation and Authorization of Chemicals)

The Safety Data Sheet (SDS) is the main and official communication tool used along the supply chain to allow safe use of chemicals. As such, BYK employs this crucial tool to communicate the REACH registration number(s), where available. In addition, BYK issues a product specific CEFIC Standard Questionnaire (SQ), for each BYK additive. This guarantees quick and easy access to first-hand information relating to relevant and individual REACH information.

You can find both the SDS and the CEFIC SQ for each BYK product at [www.byk.com](http://www.byk.com)

To inform our customers regarding Substances of Very High Concern (SVHC), we provide a half-yearly SVHC letter. This letter gives an overview concerning which of our products contain SVHC, according to the latest update of the (draft) ECHA candidate lists, as published on the ECHA-website. Please note that this information is also available in chapter 15 of the Safety Data Sheet (SDS) for each BYK product.

For all other products not contained in our homepage, please contact the BRIEF team under the following Email address: [Brief.BYK@altana.com](mailto:Brief.BYK@altana.com)

**3. Information concerning intentionally added ingredients**

The product is a combination of various substances. That is why there is no CAS number for the additive. The CAS numbers of the active ingredients are trade secrets.

**3.1 This product contains the following substances**

Ingredients	Value
1-Propylene glycol 2-methyl ether (1589-47-5)	≤ 0.1%
Total VOC, weight %	20%
Glycol ethers, also VOC & not reprotoxic class 1, 2 (EU legislation in force)	20%
Total VOC, vol. %	24%

# The direct line to the BRIEF team

Do you have a particular question on the subject of regulatory compliance and would like as precise an answer as possible – and as fast as possible, too? Then you are advised to get in touch with our BRIEF team. They will answer your queries directly and in depth. If it needs to, it will make contact with specialists or individuals to refer to in your region.

Each day the team receives inquiries from all over the world – from researchers or application engineers, for instance, who are testing new formulations or

have a query about California Proposition 65 or the issue of food contact. Buyers, too, who require concrete details for their product decisions, approach our BRIEF team. Finally, inquiries are also received from companies wanting to attach an eco-label to their products manufactured using BYK additives.

Efficient, comprehensive responses to customer queries – this is all part and parcel of our understanding of a reliable service that we have been supplying for decades.

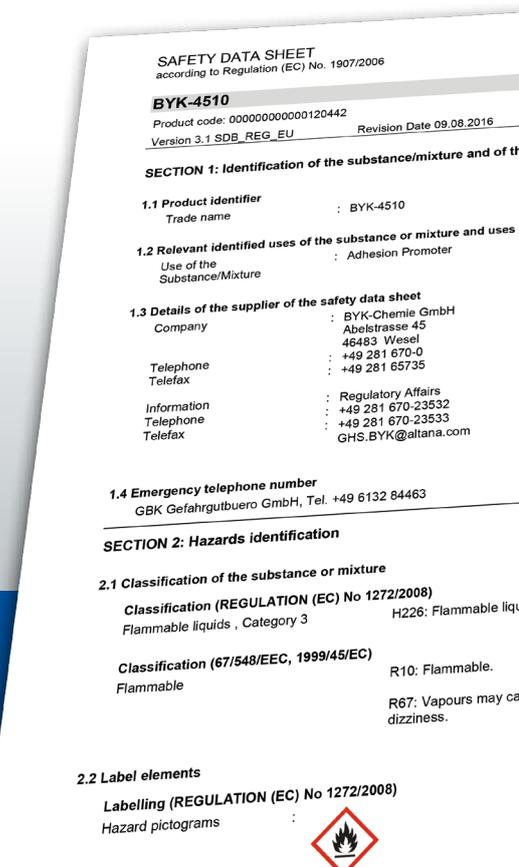


## How to get in touch with the BRIEF team

Send your question to [BRIEF.BYK@altana.com](mailto:BRIEF.BYK@altana.com). With confirmation of receipt, you will receive a reference number under which we will be processing your query. We will make every effort to reply to you as quickly and as thoroughly as possible.



Safety data sheet and label for  
shipment within the EU



**▶ Our service:**  
personal, comprehensive,  
fast and direct.

### Global data management

Our database contains all the relevant regulatory information on such aspects as standards, raw materials and product composition. It can be accessed through a multilingual keyword index. It also contains the data sheets in the particular language required, be it Japanese, English, Spanish, Russian, or another language.

As with the data sheets, we generate all the required labels and dangerous goods indicators automatically whenever we prepare our additives for shipment or export. Our labels conform to the Globally Harmonised System (GHS) of classifying and labeling chemicals, which has been adopted as standard in Europe by the CLP Regulation of the EU (governing classification, labeling and packaging). For our users in the USA, Japan, China and Korea, we have tailored them to the GHS versions currently valid there.

### Expertise for specialty areas

In Europe, REACH is an important part of regulatory compliance. We place the specialist knowledge we have acquired over the years at our customers' disposal, often in seminars or through direct dialog. In addition, we provide detailed information on our website.

On the subject of food contact, we possess extensive knowledge of the relevant country-specific regulations. This ranges from the Swiss Ordinance of Materials and Articles in Contact with Food (SR 817.023.21) via Title 21 of the U.S. Code of Federal Regulations – Food and Drugs (Title 21 CFR FDA) to the Chinese food safety standard GB 9685-2008 "Hygienic Standard for Use of Additives in Food Containers and Packaging Materials".

Likewise, we are familiar with regulations operating in the area of gas and oil production. These concern, for example, the OSPAR Convention for the Protection of the Environment of the North-East Atlantic or the main industry forum EOSCA (European Oilfield Specialty Chemicals Association).



# Worldwide network

of regulatory expertise



- 21 CFR (FDA)
- 40 CFR part 180
- Canada [DSL]
- Proposition 65
- USA [TSCA]
- ...

- 2014/312/EU (EU Ecolabel)
- EN 71-3 Toy Standard
- EU 10/2011 (PIM)
- EU 1223/2009 (Cosmetic Products)
- EU REACH
- OSPAR
- ...

At BYK, you receive with any product the relevant regulatory information, prepared for the region concerned and the laws and regulations in force there. Please contact our globally networked team of experts.



- Australia [AICS]
- China [IECSC]
- GB9685-2008
- Japan [ENCSI]
- Korea-REACH
- New Zealand [NZIoC]
- Philippines [PICCS]
- Taiwan [ECSI]



You can contact the Global Regulatory Service Team at

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