

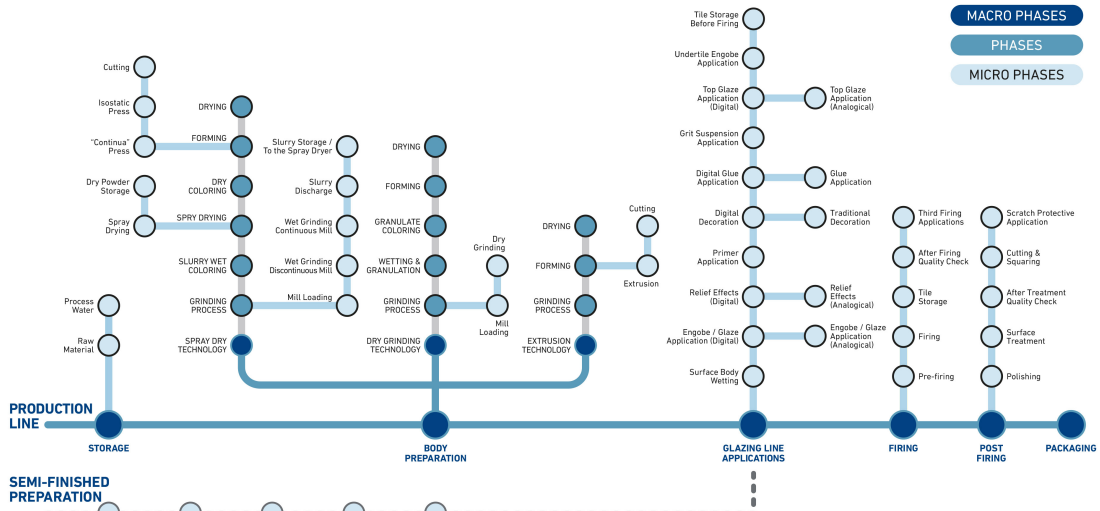


ZSCHIMMER & SCHWARZ CERAMCO

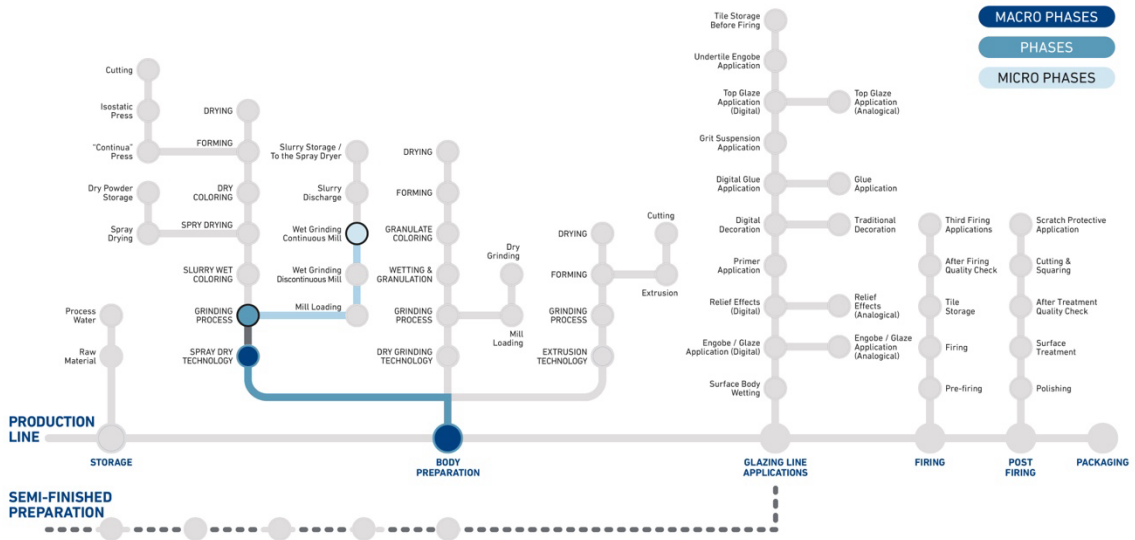
APPARENTLY INVISIBLE YET CONSTANTLY PRESENT

At every stage of the ceramic production process

A journey through problems & solutions



#68 CHEMICAL PRODUCT LABELING: A PRACTICAL GUIDE





ZSCHIMMER & SCHWARZ CERAMCO

3 | 6

It is also worth noting that this system has an indirect protective effect. Compliance with non-EU regulations is not sufficient to access the European market—products must meet EU standards. This creates a technical barrier to entry that safeguards both the market and high safety levels.

This approach is particularly evident for biocides—products designed to control harmful organisms such as bacteria, viruses, fungi, or insects—which therefore require especially strict oversight. The key reference is Regulation (EU) No. 528/2012 (BPR), in force since 2013, replacing earlier legislation with a more harmonized and stringent framework.

At its core, the principle is clear: no chemical substance or biocidal product can be placed on the market without prior evaluation and approval. This process is coordinated by **ECHA** (the European Chemicals Agency) together with national authorities. Authorization requires proof of both efficacy and safety, supported by technical dossiers, testing, and administrative procedures—often involving significant investment. This highlights how structured and rigorous the European control system is.

2. Biocides, treated articles, sanitizers, and sector-specific rules

One of the most complex aspects is distinguishing between different product categories, each governed by different rules.

A **biocidal** product is designed to destroy, deter, or control harmful organisms. To be marketed, it must demonstrate effectiveness and receive authorization for specific uses. Approval is not general—it is tied to defined applications, meaning a substance may be effective (or authorized) in one context but not in another.

Treated articles, on the other hand, are objects that have been treated with or intentionally incorporate biocidal substances—such as antibacterial fabrics, anti-mold paints, treated building materials, or surfaces designed to inhibit microbial growth. In this case, what is marketed is not the substance itself but a finished product with a specific function, subject to different regulatory obligations.

Biocides and products containing biocides for preservation purposes are regulated differently. A treated material, for example, does not fall under the biocidal product directive and does not require registration, unlike the biocide itself, which must be approved by ECHA. By contrast, products labelled as “sanitizing” do not require registration.

This leads to another layer of complexity: terms such as “sanitizer” or “disinfectant” are not formally defined under biocidal legislation, allowing such products to be marketed more freely.

Treated articles can only be sold if the biocidal active substances they contain are already approved or under evaluation according to EU rules. This serves as a key preventive safeguard.

A specific category is that of **medical surgical disinfectants (in Italian: Presidi Medico-Chirurgici - PMC)**, registered nationally with the Ministry of Health. These products must demonstrate both safety and effectiveness and are subject to dedicated requirements. A well-known example is Amuchina, widely recognized for its disinfectant and biocidal properties.

Not all products follow the same regulatory path. Certain sectors are governed by specific frameworks that may override or exclude CLP requirements. Cosmetics, for instance, may contain biocidal substances such as preservatives but are not subject to CLP labelling when intended for end users. The same applies to medicinal products and food-contact materials. These are not exceptions, but rather distinct regulatory regimes.

Commercial claims also play a critical role.



ZSCHIMMER & SCHWARZ CERAMCO

4 | 6

Terms like *antibacterial*, *bactericidal*, or *antimicrobial* are not just marketing language—they imply a specific action of an active substance and may bring a product within the scope of biocidal regulation.

3. Labelling, safety data sheets, and responsibility

It is essential to clearly distinguish between CLP labelling and other product information requirements. CLP labelling applies only to hazardous substances and mixtures and includes specific elements such as hazard pictograms, hazard statements, and precautionary statements. Labels must be visible, legible, durable, and written in the language of the country where the product is sold. However, the label alone is not sufficient. The core source of information is the Safety Data Sheet (SDS), a structured document divided into 16 sections that accompanies the product throughout its lifecycle.

The SDS identifies the product and the responsible company, but more importantly, it provides detailed information on composition. Hazardous components must be disclosed, ensuring transparency about the sources of risk.

It also provides **clear guidance on how to respond in case of incidents**. Rather than simply stating that a product is hazardous, it explains what actions to take. For example, in case of eye contact, immediate rinsing is required; in case of ingestion, inducing vomiting may not be appropriate, especially with corrosive substances or those posing a choking risk. These instructions are critical in the first moments after an accident.

The SDS also specifies appropriate **personal protective equipment**—not in general terms, but in detail (types of gloves, eye protection, masks, ventilation systems, etc.). In industrial settings, this information is essential for building effective safety procedures.

Storage conditions are also addressed. Some products must be kept away from heat, others from incompatible substances. For example, acids and bases can react violently if mixed following a spill. In **fire situations**, the SDS is equally vital. Emergency responders need to know which substances are present, as some may release toxic fumes during combustion. For this reason, safety data sheets should always be readily accessible. Environmental aspects are also covered, including biodegradability, persistence, and toxicity—helping to prevent contamination.

Transport information is included as well, such as ADR classification and required precautions under the European Agreement concerning the *International Carriage of Dangerous Goods by Road*.

It is important to note that an SDS is not always mandatory. For non-hazardous products, it may be replaced by an information sheet. However, when required, it must be provided free of charge and be traceable—the supplier must be able to prove it was delivered.

This brings us to a key issue: responsibility. Failure to comply with regulatory requirements can lead to significant penalties, including criminal liability in serious cases. These are not merely formal obligations—they directly impact safety and corporate accountability.

4. UFI, poison centers, and emergency response

One of the most important recent tools is the **UFI** (Unique Formula Identifier), an alphanumeric code that uniquely identifies a chemical mixture.

Its value becomes clear in emergencies. If someone accidentally ingests or is exposed to a product, healthcare professionals can use the UFI to retrieve detailed information about its composition.



ZSCHIMMER & SCHWARZ CERAMCO

5 | 6

Poison centers across Europe have access to this data and can quickly recommend appropriate treatment.

This system allows companies to keep formulations confidential while ensuring that critical information is available when needed. It shows how regulation is not just a constraint, but also a practical support tool for emergency management.

Beyond its operational role, the UFI also demonstrates that product information is not intended solely for the end user. In an emergency, it activates a chain of technical and medical response, turning the label into a real safety tool. In the EU system, labelling is therefore not just a formal requirement, but an integral part of risk management.

Regulatory evolution, emerging risks, and misuse of substances

Chemical substances can present a wide range of hazards: irritation, corrosion, flammability, toxicity, and environmental risks, as well as more complex categories such as carcinogens and reproductive toxins.

Regulation is constantly evolving as scientific knowledge advances. Some risks—like those linked to asbestos—only became apparent decades later. While efforts are now made to anticipate such risks, ongoing adaptation remains essential.

New hazard classes include endocrine disruptors, substances capable of interfering with hormonal systems. This is an emerging field that is expected to gain increasing importance.

Another key issue is “dual use”: certain substances, while having legitimate industrial applications, can also be used to produce chemical weapons. As a result, strict controls, information requirements, and sales restrictions—particularly for consumers—are in place.

This dynamic also applies to biocides. The list of approved substances is regularly updated, and particularly critical categories—such as persistent substances or those with complex toxicological profiles—are subject to increasingly stringent restrictions.

There are also areas where interpretation is not always straightforward, such as defining the primary biocidal function or managing commercial claims. In many cases, assessment must be carried out on a product-by-product basis, supported by guidance documents and regulatory interpretations. This makes continuous updates essential for companies, professionals, and operators in the field.

5. Use, transport, and differences between users

Safety depends not only on a product’s composition, but also on how it is used.

In industrial settings, advanced control systems and structured procedures are in place. Professional users rely on specific expertise to manage risks.

Consumers, however, represent the most critical point, as they use products without technical training. For this reason, many hazardous products are restricted to professional use and are not available to the public.

Transport is another critical factor. Some substances require trained personnel, specialized equipment, and strict procedures to handle potential incidents such as spills or fires.

These differences between user groups are also reflected in information requirements. Industrial environments benefit from training, procedures, protective equipment, and structured controls. Professional settings maintain these safeguards, though often to a lesser extent. The end consumer, by contrast, is the most vulnerable link in the chain, lacking technical expertise. As a result, regulations adjust product availability, information obligations, and marketing practices according to the intended user.



ZSCHIMMER & SCHWARZ
CERAMCO

6 | 6

6. Conclusions: understanding to ensure safe use

The European regulatory framework for chemicals is complex, but it follows a clear logic. REACH, CLP, and BPR work together to ensure safety, transparency, and control.

The label provides the first level of communication, the Safety Data Sheet is the operational backbone, and the UFI enables effective emergency response.

Understanding these tools is not only about regulatory compliance—it is about using chemical products responsibly, reducing risks, and improving safety at every stage of their lifecycle.

When it comes to biocides and products containing or incorporating them, this understanding requires an additional level of attention: recognizing whether you are dealing with a substance or mixture under CLP, a biocidal product regulated by the BPR, or a treated article subject to specific information requirements.

Making these distinctions is not just a theoretical exercise—it is essential for correct compliance, accurate communication, and truly effective risk management.

www.zschimmer-schwarz-ceramco.it
www.ceramco.it