

Biochrom AG introduces new hazard labels

Information from Biochrom AG, January 17, 2011

Since December 2010, substances need to be labelled using new hazard symbols based on an international standardised system in order to comply with the EU regulation on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). After a certain transitional period, previously used symbols, such as the black skull and crossbones on orange background, may no longer be used. From 2015, mixtures need to be labelled in a standardised manner and in accordance with the new system.

The new hazard symbols feature red diamond frames with black symbols on a white background. The previous symbols (pictograms) are added by some new ones, while certain symbols (such as the X symbol with its many different meanings) no longer apply. Beneath the hazard pictograms, you may additionally find the signal words "warning" or "danger". The new system features more criteria to rate hazards and new classification criteria. This may lead to the fact that certain products are classified differently with regard to the hazards they pose. H statements (hazard statements) and P statements (precautionary statements) replace the R and S phrases that have been used in the past.

Biochrom AG is already using the new system for its substances and mixtures of substances, such as collagenase, trypsin and HEPES dry substance. As a consequence, safety data sheets for those products have been revised completely. During the transitional period, classification and labelling of mixtures will then be phased in to the new system as well.

The following summarises all changes. The most important facts on labelling hazardous materials can be found in the FAQ section in point 6.

1 GHS: new system for the classification and labelling of chemicals

It is generally required to classify chemicals by hazards and to label them accordingly. This helps prevent adverse effects for the environment and human beings when dealing with chemicals. To date, various different systems have been used worldwide, which led to dangerous misunderstandings among users and problems relating to transport and safety at work.

This induced the United Nations to agree upon globally binding criteria that the organisation combined in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The Regulation (EC) No 1272/2008 (CLP) on classification, labelling and packaging of substances and mixtures stipulates the implementation of the harmonised system within the European Union.

The new system is being introduced gradually, with the transitional period for substances having ended on December 1, 2010. This means that all solids need to be labelled in accordance with the new system. In the case of Biochrom AG, this refers to antibiotics, such as G 418-BC and streptomycin sulphate, buffers, such as HEPES dry substance, or enzymes, such as trypsin (see table 1). The transitional period for mixtures, i.e. liquids (such as buffers or other sterile liquids from Biochrom AG), will end on June 1, 2015.

2 Changes at a glance

2.1 Product classification

The new system differs between hazard classes and hazard categories.

- 28 hazard classes (replacing the former 15 hazard categories of danger)
- hazard categories define each hazard based on the respective hazard severity

To some extent, the classification criteria differ from those criteria given in the previous dangerous preparations and dangerous substances directives. For example, the pictogram “skull and crossbones” applies only to acute toxic effects from now on. Chronic health effects, such as carcinogenic, mutagenic or reprotoxic effects, are labelled using a new pictogram (“health hazard”).

2.2 Label elements


















A total of nine hazard pictograms with a red diamond frame have been chosen to visualise the individual hazards, replacing the orange hazard symbols previously used.

- New pictograms include “gas cylinder”, “exclamation mark” and “health hazard”.
- New signal words define the potential hazard level.
 - “danger”: signal word indicating severe hazard categories
 - “warning”: signal word indicating less severe hazard categories
- New hazard statements (H statements) replace R phrases. Hazard statements define the type and the severity of the hazard posed by a dangerous substance or mixture.
- New precautionary statements (P statements) replace S phrases. Precautionary statements define recommended measures to minimise or prevent adverse effects that result from the exposure to a dangerous substance or mixture when dealing with it or disposing of it.

3 New hazard symbols at a glance

GHS introduces new pictograms for the labelling of dangerous substances and mixtures. For example, the meaning of the familiar pictogram for “corrosion” has been extended adding a corrosive effect on metals. The pictogram “skull and crossbones” does now only apply to acute toxicity. Chronic toxicity has been assigned a new pictogram. The following table 1 gives you a detailed overview.

tab. 1: new hazard symbols

new symbol	description, label, effects	precautions	replaced symbol
	Skull and crossbones (GHS06) Causes serious health problems or death immediately, even in smaller quantities.	Do not inhale, touch or swallow. Wear protective clothing. Call poison centre or doctor/physician immediately. Ensure recovery position.	 
	Health hazard (GHS08) Allergenic, carcinogenic, mutagenic; may damage fertility, the unborn child or organs.	Obtain detailed information before dealing with such substances. Wear protective clothing and gloves, wear safety glasses and mask or respiratory protection.	
	Corrosion (GHS05) Corrosive to metals and body tissue. May cause severe eye damage.	Avoid contact. Wear safety glasses and protective gloves. In case of eye and skin contact, wash with water.	 
	Exclamation mark (GHS07) Causes health problems, as well as eye, skin or respiratory irritation. In larger quantities, causes death.	See "corrosion". In case of skin irritation or eye contact, wash with water or appropriate agent.	 
	Environment (GHS09) Adverse, toxic or very toxic effects on aquatic organisms, acute or with long-term effect.	Dispose of as hazardous waste. Do not allow to enter the environment.	
	Flame (GHS02) Flammable. Liquids produce explosive mixtures with air. Produces flammable gases with water or is spontaneously ignitable.	Keep away from open flames and sources of heat. Keep vessels tightly closed and fireproof.	
	Exploding bomb (GHS01) Fire, shocks, friction, and heating cause explosion. Hazard posed by fire, air pressure and splinters.	Avoid frictions, shocks, fire, sparks, and any heat generation.	
	Flame over circle (GHS03) Oxidising and intensifies fires. Produces explosive mixtures if mixed with flammable substances.	Keep away from flammables and avoid mixing. Keep clean.	
	Gas cylinder (GHS04) Gas cylinders under pressure may explode if exposed to heat. Cryogenic gases produce cold burns.	Do not heat. In case of cryogenic gases, wear protective gloves and safety glasses.	



4 New labelling for Biochrom AG products




Biochrom AG products are subject to the new labelling requirements. Labels of solids do already include the new hazard symbols. Safety data sheets have been revised accordingly.




- **Please note:** Between December 1, 2010, and June 1, 2015, safety data sheets need to include both classifications, i.e. the classification in accordance with EU regulations and provisions **as well as** the new GHS classification. The product label, however, does only show the GHS classification.


The following table 2 gives an overview on how Biochrom AG products are being labelled in safety data sheets from now on in accordance with the new regulations.

tab. 2: new labels for Biochrom AG products; status: December 1, 2010

product	cat. no.	new labels and classification
trypsin	L 2103-20G	<p>hazard symbols:</p>  <p>signal word: danger</p> <p>hazard statements: H315 – Causes skin irritation. H319 – Causes serious eye irritation. H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 – May cause respiratory irritation.</p> <p>precautionary statements: P302 + P352 – If on skin: Wash with plenty soap and water. P305 + P351 + P338 – If in eyes: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. P304 + P341 – If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P342 + P311 – If experiencing respiratory symptoms: Call a poison centre or doctor / physician.</p>
collagenase	C 1-22, C 1-28, C 2-22, C 2-28, C 3-22, C 3-28, C 4-22, C 4-28	<p>hazard symbols:</p>  <p>signal word: danger</p> <p>hazard statements: H315 – Causes skin irritation. H317 – May cause an allergic skin reaction. H319 – Causes serious eye irritation. H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 – May cause respiratory irritation.</p> <p>precautionary statements: P261 – Avoid breathing dust / fume / gas / mist / vapours / spray. P280 – Wear protective gloves / protective clothing / eye protection / face protection. P302 + P352 – If on skin: Wash with soap and water.</p>

		<p>P304 + P341 – If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305 + P351 + P338 – If in eyes: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</p> <p>P342 + P311 – If experiencing respiratory symptoms: Call a poison centre or doctor / physician.</p>
amphotericin B	A 2610	<p>hazard symbol:</p>  <p>signal word: warning</p> <p>hazard statements: H302 – Harmful if swallowed. H315 – Causes skin irritation. H319 – Causes serious eye irritation. H335 – May cause respiratory irritation</p> <p>precautionary statements: P261 – Avoid breathing dust / fume / gas / mist / vapours / spray. P264 – Wash concerned body parts thoroughly after handling. P280 – Wear protective gloves / protective clothing / eye protection / face protection. P305 + P351 + P338 – If in eyes: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</p>
G418-BC	A 291-25	<p>hazard symbols:</p>  <p>signal word: danger</p> <p>hazard statements: H317 – May cause an allergic skin reaction. H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled. H360D – May damage the unborn child.</p> <p>precautionary statements: P201 – Obtain special instructions before use. P261 – Avoid breathing dust / fume / gas / mist / vapours / spray. P280 – Wear protective gloves / protective clothing / eye protection / face protection. P281 – Use personal protective equipment as required. P308 + P313 – If exposed or concerned: Get medical advice / attention.</p>
gentamycin sulphate	A 271-23, A 271-25, A 271-26	<p>hazard symbols:</p>  <p>signal word: danger</p> <p>hazard statements: H315 – Causes skin irritation. H317 – May cause an allergic skin reaction. H319 – Causes serious eye irritation. H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p>

		precautionary statements: P261 – Avoid breathing dust / fume / gas / mist / vapours / spray. P280 – Wear protective gloves / protective clothing / eye protection / face protection. P342 + P311 – If experiencing respiratory symptoms: Call a poison centre or doctor / physician.
penicillin G sodium salt	A 321-42, A 321-44	hazard symbol:  signal word: danger hazard statements: H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. precautionary statements: P261: Avoid breathing dust / fume / gas / mist / vapours / spray. P280: Wear protective gloves / protective clothing / eye protection / face protection. P302 + P352: If on skin: Wash gently with plenty of soap and water. P304 + P341: If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P342 + P311: If experiencing respiratory symptoms: Call a poison centre or doctor / physician.
polymyxin B-sulphate	A 231-40	hazard symbol:  signal word: warning hazard statements: H302 – Harmful if swallowed. precautionary statements: P264 – Wash concerned body parts thoroughly after handling. P301 + P312 – If swallowed: Call a poison centre or doctor / physician if you feel unwell.
streptomycin sulphate	A 331-26, A 331-27	hazard symbols:  signal word: danger hazard statements: H302 – Harmful if swallowed. H317 – May cause an allergic skin reaction. H332 – May be harmful if inhaled. H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled. H361 – Suspected of damaging fertility or the unborn child. precautionary statements: P261: Avoid breathing dust / fume / gas / mist / vapours / spray. P264: Wash concerned body parts thoroughly after handling. P280: Wear protective gloves / protective clothing / eye protection / face protection. P342 + P311: If experiencing respiratory symptoms: Call a poison centre or doctor / physician.

HEPES dry substance	L 1603	<p>hazard symbol:</p>  <p>signal word: warning</p> <p>hazard statements: H315 – Causes skin irritation. H319 – Causes serious eye irritation. H335i – May cause respiratory irritation.</p> <p>precautionary statements: P261 – Avoid breathing dust / fume / gas / mist / vapours / spray. P280 – Wear protective gloves / protective clothing / eye protection / face protection. P304 + P341 – If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 – If in eyes: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</p>
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5 Questions and answers regarding the new labelling

5.1 Why has the previous and proven system been revised?

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) has been implemented with the intention to reach a standardised manner to label of substances on a worldwide scale. For in the past, substances had been labelled differently, possibly leading to misunderstandings. In 1992, the United Nations thus decided to set up a globally harmonised classification and labelling system for substances. In the meantime, the GHS has been transposed into EU legislation by implementing an EU regulation (CLP regulation).

5.2 What does CLP stand for?

The CLP regulation is the new EU regulation on **C**lassification, **L**abelling and **P**ackaging of chemical substances and mixtures. Within the European Union (EU), all chemicals have to be classified and labelled in accordance with this regulation. The CLP regulation is based on the GHS.

5.3 How do GHS and the CLP regulation differ?

The CLP regulation is legally binding for EU member states, whereas the GHS is not legally binding.

GHS and the CLP regulation are not identical, as the basis of the CLP regulation does additionally include previous EU classification and labelling legislation.

5.4 When did the CLP regulation take effect?

The CLP regulation took effect in 2009 and applies to all EU member states. It gradually replaces the dangerous substances directive 67/548/EEC, as well as the dangerous preparations directive 1999/45/EC, which will be no longer in force from June 2015.

The transitional period of the CLP regulation on substances has already ended: all substances need to be labelled in accordance with the new system since December 1, 2010. For mixtures (solutions), however, the CLP regulation on labelling will become binding only as from June 1, 2015. In both cases, users will be able to continue selling stocks with outdated labels for two more years.

5.5 What Biochrom AG products are concerned by the new labelling criteria?

Antibiotics, enzymes and buffers from Biochrom AG are being labelled according to the new system (goods in stock may be labelled with outdated symbols until 2012). For Biochrom AG's sterile liquids, such as buffers and solutions, the transitional period applies (until 2015). This accounts for the fact that labels for lots of one product may differ.

5.6 What aspects do I need to consider as a user?

In accordance with the new CLP regulation, some substances may be classified differently now. In any case, users should continue to deal with substances with due caution. Please remember: Obtain detailed information and prepare your protective equipment before dealing with the substance. You will find up-to-date information on the respective substance in the safety data sheet, which each manufacturer has to provide.

5.7 I still possess Biochrom AG products with outdated labels. Can I still use them?

Yes, you may continue to use them. All updated safety data sheets include both the new and the previous labelling of the products, as well as information on how to deal with them. You may download safety data sheets on our homepage at: www.biochrom.de.

5.8 Where do I find classification data for a product that has been labelled using the new symbols?

Biochrom AG's safety data sheets include both the new and the previous labelling. You may access and download these safety data sheets on the Biochrom AG homepage. Databases such as euSDB (see References) allow users to access safety data sheets from a wide range of manufacturers.

5.9 The new safety data sheet version for Biochrom AG products looks completely different now. What data do the new safety data sheets include?

The safety data sheets have been revised, as the CLP regulation classifies and labels hazards differently. Until 2015, each safety data sheet has to include both the new and the previous labelling. In addition, the data sheets include major figures in order to allow for a reliable identification, such as the CAS or EC number of a substance. A further innovation is the fact that necessary protective equipment is being labelled using respective symbols.

5.10 Where do I find Biochrom AG's safety data sheets?

You can access Biochrom AG's safety data sheets on our homepage. In addition to detailed product information, you can access the respective safety data sheet for each product. You may use the following link in order to search for a certain safety data sheet, entering the catalogue number of the product: <http://www.biochrom.de/en/service/safety-data-sheets/>

5.11 What do I need to do in case of poisoning symptoms?

If you are located in Germany, you may use the poison centre hotline that Biochrom AG has set up. The poison centre is available 24 hours a day, seven days week:

GIZ-Nord – Giftinformationszentrum-Nord, Göttingen

Phone: +49 (0)551-383180 or via e-mail: giznord@giz-nord.de

If you are located outside of Germany, please contact a poison centre or a physician in your respective country.

6 References

- **Biochrom AG safety data sheets, search feature:**
<http://www.biochrom.de/en/service/safety-data-sheets/>
- **overview on Biochrom AG's safety data sheets** (search index for safety data sheets, Johannes Gutenberg University Mainz, department for occupational safety, project euSDB) <http://www.eusdb.de/en/search/results>
- information from the Bundesinstitut für Risikobewertung (BfR, the German Federal Institute for Risk Assessment), „Neue Gefahrenkennzeichnungen auf Verpackungen“ (new hazard labelling on packaging), Berlin 2008
www.bfr.bund.de/cm/238/neue_gefahrenkennzeichnungen_auf_verpackungen.pdf
(data available only in German)
- Berufsgenossenschaft der chemischen Industrie (BG Chemie, the German institution for statutory accident insurance and prevention in the chemical industry) 2011: GHS – Global Harmonisiertes System zur Einstufung und Kennzeichnung von Chemikalien (GHS - Harmonized System of Classification and Labelling of Chemicals)
<http://www.bgchemie.de/REACH-GHS> (data available only in German)