

Agfa Policy on CMR substances and mixtures

Legal background

Regulation (EC) No 1272/2008 – also known as the CLP-Regulation – is the European Regulation on Classification, Labelling and Packaging of substances and mixtures, which repealed the former European Directives 67/548/EEC and 1999/45/EC – respectively known as DSD (Dangerous Substance Directive) and DPD (Dangerous Preparation Directive).

The CLP-Regulation aligns the EU classification system to the United Nations GHS directive (Globally Harmonised System of Classification and Labelling of Chemicals). GHS is an internationally agreed-upon system, designed to replace the various classification and labelling standards used in different countries by one worldwide system using more consistent criteria for classification and labelling on a global level.

GHS aims to protect workers, consumers and the environment by means of classification, labelling and safety data sheets which reflect hazards of chemicals.

Besides the EU, numerous other countries have already adopted GHS, replacing their former national chemicals hazard classification and communication legislation.

In GHS a CMR substance is a substance classified as Carcinogenic, Mutagenic or toxic for Reproduction, whereby a substance is:

- carcinogenic when there is a potential effect of exposure to the substance and development of cancer in humans,
- mutagenic when there is a potential effect of exposure to the substance and inducement of heritable mutations in the germ cells in humans,
- toxic for reproduction when there is a potential effect of exposure to the substance and inducement of an adverse effect on development of the unborn child or on fertility of humans.
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Depending on available evidence GHS distinguishes between CMR substances in three categories, which are defined as follows:

- category 1A: known human CMR - classification is based on human evidence (epidemiological data)⁽¹⁾,
- category 1B: presumed human CMR - classification is based on animal evidence⁽²⁾,
- category 2: suspected human CMR - classification based on evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B⁽³⁾.

According to CLP, a chemical mixture is classified as carcinogenic, mutagenic or toxic to reproduction of category 1A, 1B or 2, when it contains one or more components classified as CMR at a concentration equal or higher to concentration limits defined in Annex I to CLP⁽⁴⁾.

As knowledge on the toxicological properties of substances continuously evolves (eg. through tests performed in the EU REACH registration or other EU REACH processes), substances from time to time are reclassified from one toxicity category into another. This in its turn triggers a reclassification of mixtures containing the reclassified substance.

⁽¹⁾ note that CMR cat. 1A was named in the former European regulations DSD and DPD: category 1.

⁽²⁾ note that CMR cat. 1B was named in the former European regulations DSD and DPD: category 2.

⁽³⁾ note that CMR cat. 2 was named in the former European regulations DSD and DPD: category 3.

⁽⁴⁾ note that other differences between DSD/DPD and CLP also include that the concentration threshold to classify and label a mixture containing a reprotoxic substance as a ' reprotoxic mixture' is reduced in the CLP regulation in comparison to the previously applicable threshold in the DPD:

- the threshold was lowered from 0.5% to 0.3% for a cat. 1A or cat. 1B (formerly in DPD cat. 1 or cat. 2)
- the threshold was lowered from 5% to 3% for a cat. 2 (formerly in DPD cat. 3) substance that is toxic for reproduction.

Other countries who have implemented GHS may use different threshold values.

Policy on the use of CMR substances in Agfa products

In accordance with Agfa's corporate commitment to bring safe products to the market, all mixtures supplied by Agfa-Gevaert, including eg. photographic processing solutions, prepress chemicals, inks, etc..., are developed and manufactured in compliance with legal and with internal guidelines.

As a consequence the toxicological and the ecotoxicological properties are considered as an important element in the selection of chemicals to be used in commercial Agfa products. This in order to minimise the use of chemical ingredients that could have adverse effects on the health of our workers and our customers or have adverse effects on the environment.

The toxicological and the ecotoxicological properties of chemical substances used are being monitored and actioned upon throughout every life cycle phase of the Agfa product.

The design and market introduction phase of an Agfa product:

Agfa products by design do not contain any CMR category 1A or category 1B substances at market introduction.

CMR category 2 substances are allowed to be used during the design of Agfa products only if after technical investigation it is found and motivated not possible to avoid the use for a specific application and after safe use has been proven.

The active life cycle phases of an Agfa product:

In the event that after its market introduction an Agfa product is reclassified and re-labelled to a CMR category 1A or 1B mixture, due to a change in classification of one of its substances, then a substance substitution programme will be started. The results of that research will regularly be reported to the Corporate Safety, Health & Environment department.

In the event of a reclassification a tailored communication with the Customers concerned will be set up on Agfa's intentions, whereby Agfa will make all reasonable efforts possible to assure the continuity of the supply during the period needed for substitution.

In the event of reclassifications of CMR substances up to cat. 1B:

if after technical investigation, it is found and motivated not to be possible to avoid at that time the use of the substance, then an exemption can be given by the Corporate Safety, Health & Environment department after safe use has been proven, whereby it is still expected that the CMR category 1B substance is replaced as soon as technically possible

The Agfa products, wherein CMR category 1B substances are used, are critically reviewed on a yearly base by the interdisciplinary Rationalisation Commission on Chemistry, presided by the Corporate Safety, Health & Environment department, whereby the possibilities for replacement are re-evaluated.

The risks and preventive measures for users of the mixtures containing CMR substances, are systematically described in the respective safety data sheets.

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