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Federal Department of Home Affairs FDHA

Federal Office of Public Health FOPH
Consumer Protection Directorate

Note

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Section REACH and Riskmanagement

Practical application of the "Short guidance on the use of in vitro test methods for the classification of products/mixtures for skin corrosion (H314)" to some marketed mixtures.

Eleven chemical products available on the Swiss market were submitted to the step-by-step practical procedure proposed in the "Short guidance on the use of in vitro test methods for the classification of products/mixtures for skin corrosion (H314)" published by the Division of Chemicals, Swiss Federal Office of Public Health. All eleven products are currently classified H314 (causes severe skin burns and eye damage) according to the information in their safety data sheets (SDS).

It is recognized that the additivity approach of CLP may overestimate the corrosive hazard of mixtures containing corrosive components. On the other hand, an extreme pH value (2.5 ≤ pH ≥11.5) does not always means that the mixture is corrosive to the skin. The proposed step-by-step practical procedure aims to demonstrate that in certain cases a mixture may not be considered as corrosive based on the result of an *in vitro* test. The application of *Bridging principle* is not considered in this evaluation.

Mixtures with skin corrosive hazard (labelled H314) present a high risk of accident for private consumer and regulatory risk reduction measures are justified. According to the Chemical ordinance (ChemO) mixtures labelled "GHS 05 , H314" are assigned to Group 2 and are excluded from retailing in self-service areas for private consumers (art. 63 in conjunction with annex 5 ChemO). Therefore it may be advantageous for the manufacturer to rely on *in vitro* testing and to make use of the flexibility proposed in the CLP regulation to achieve a more realistic classification and labelling of their products.

The objective of this evaluation is to evaluate if some products may be excluded from a classification as skin corrosive (H314) and consequently not be assigned to Group 2 according to Annex 5 ChemO. The irritant potency to skin (OECD TG 439) is not evaluated. Without further testing, it may be assumed that the products which are not skin corrosives are irritant to the skin (H315).

The choice of the *in vitro* test was based on pH consideration. Products with extreme pH (2.5 ≤ pH ≥11.5) were tested with OECD TG 435, other products were tested with OECD TG 431.

The following table shows the results of the step-by-step practical procedure:

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Product [1]	corrosive / irritant components according to SDS	pH	Acid/alkaline Reserve Result of Young Formula [2]	OECD Test applied	Result *in vitro* test	Group 2 according to Annex 5 ChemO [3] yes / no
Product 1	C R34: 5% C R35: 1%	12.3 (extreme)	< 14.5 possibly non corrosive	TG 435	non corrosive	no
Product 2	C R34: 5% Xi R36: 25% Xi R41: 12.5%	1.7 (extreme)	> -0.5 possibly non corrosive	TG 435	non corrosive	no
Product 3	C R35: 5% C R34: 5% Xi R36/38: 5%	1.1 (extreme)	> -0.5 possibly non corrosive	TG 435	category 1 C	yes
Product 4	C R34: 10% Xi R 36/38: 65%	7.4	n.a.	TG 431	non corrosive	no
Product 5	H314: 5% H318: 10% H319: 5%	13.3 (extreme)	< 14.5 possibly non corrosive	TG 435	category 1 C	yes
Product 6	C R34: 10%	12.3 (extreme)	reserve not tested	TG 435	non corrosive	no
Product 7	C R34: 10% Xi R36: 5%	7.7	n.a.	TG 431	non corrosive	no
Product 8	C R34: 25%	0.9 (extreme)	reserve not tested	TG 435	category 1 B	yes
Product 9	H314: 10% H315: 20% H319: 10%	13.4 (extreme)	< 14.5 possibly non corrosive	TG 435	category 1 C	yes
Product 10	H314: 50% H319: 10%	0 (extreme)	< -0.5 corrosive	TG 435	category 1 B	yes
Product 11	H314: 10%	13.5 (extreme)	< 14.5 possibly non corrosive	TG 435	category 1 B	yes

[1] All products in this table are classified H314 according to the Safety Data Sheet (SDS) of the manufacturer, based on CLP additivity approach or extreme pH. SDS indicate that products 1 to 9 were classified as irritant (Xi) according to directive 1999/45/EC.

[2] Products with extreme pH should be considered corrosives if the result of the Young formula is ≥ 14.5 or ≤ - 0.5. If not, the products should not be considered as corrosive based on extreme pH, but non-corrosivity should be confirmed.

[3] As a result of the step-by-step procedure proposed in the "Short guidance on the use of in vitro test methods for the classification of products/mixtures for skin corrosion (H314)" it can be demonstrated that some products may not be classified as corrosive category 1, H314. If not classified and not labelled H314, products are not assigned to Group 2 according to Annex 5 ChemO (based on their corrosive hazard) and may be retailed in self-service.

Conclusion

Products 10 and 11 which are classified skin corrosives according to CLP and Directive 1999/45/EC, in accordance with their SDS, are also corrosives in *in vitro* tests.

Products 1 to 9 are classified H314 (CLP) and Xi (Directive 1999/45/EC) in accordance with their SDS. Five over nine products may not be classified as skin corrosive category 1 (H314) following the step-by-step approach propose in the "Short guidance on the use of in vitro test methods for the classification of products/mixtures for skin corrosion (H314)".

Products that are not classified and labeled H314 in application of the step-by-step procedure may be sold in Switzerland to private consumer in self-service area. The SDS should indicate under chapter 11 the application and the result of the *in vitro* test. The Swiss enforcement authority may ask the manufacturer to present the report of the *in vitro* test.

In case of export to EU member states it is recommended to verify with the national authority if they accept this approach.

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