

16 August 2016

Notification about change of classification of TMPTGE

Substance Name: Reaction mass of 1-(2,3-epoxypropoxy) -2,2-bis (2,3-epoxypropoxy) methyl) butane and 1-(2,3-epoxypropoxy) -2-(2,3-epoxypropoxy) methyl) -2-hydroxymethyl butane (also known as TMPTGE)

CAS Number: 30499-70-8

New data made available in the framework of the REACH registration of the above mentioned substance has indicated effects requiring the **reclassification of the substance under CLP GHS rules**.

TMPTGE must thus be reclassified and labeled as follows:

From:



Skin irritant category 2, H315: Causes skin irritation
Eye irritant category 2, H319: Causes serious eye irritation
Skin sensitizer category 1, H317: May cause an allergic skin reaction
Aquatic chronic category 3, H412: Harmful to aquatic life with long lasting effects

To:



Skin Corrosive category 1C, H314: Causes severe skin burns and eye damage
Eye damage category 1, H318: Causes serious eye damage
Skin sensitizer category 1B, H317: May cause an allergic skin reaction
Reprotoxic category 1B, H360F: May damage fertility
Aquatic chronic category 2, H411: Toxic to aquatic life with long lasting effects

Reason for reclassification

The reclassification is based on the results of a reproduction/developmental screening study by oral route in rats (OECD 422), done upon request of ECHA in the framework of the REACH registration of TMPTGE¹.

In this study, for the multi-constituent substance TMPTGE, the No Observed Adverse Effect Level (NOAEL) for systemic toxicity was determined to be 300 mg/kg bw/day (highest dose level tested). At the same dose level all female animals failed to achieve pregnancy indicating a clear effect of the substance on reproduction. The NOAEL for reproduction was therefore considered to be 100 mg/kg bw/day.

Additionally, an investigative oral reproduction study was conducted at a dose level of 300 mg/kg bw/day with the substance. The design of the study was similar to the above mentioned OECD 422 study with two groups in which male animals treated with the substance were mated with untreated female animals (group 1) and untreated male animals were mated with treated female animals (group 2), respectively. In this study all female animals from group 1 failed to achieve pregnancy indicating a clear fertility problem with the male animals. Pregnancy rate in group 2 was not affected.

There is clear evidence of an adverse effect on sexual function and fertility in the absence of other toxic effects and, therefore, according to UN GHS, the substance has to be classified as "Reprotoxicant Cat.1B, H360F: May damage fertility".

Regulatory requirements

This change of classification and the attached labeling requirements should equally apply to **all products containing the substance CAS 30499-70-8 at a concentration greater or equal to 0.3%**, including products that may be regarded as polymers.

Given the serious health indications, all products, irrespective of their polymeric nature, which contain significant concentrations of the substance CAS 30499-70-8 should be reviewed, reclassified and labeled according to GHS rules.

For further information, please contact: Anne-Marie.Hamilton@PlasticsEurope.org

The information above is provided in good faith to give general guidance based on knowledge gathered at the time of writing and does not replace the need for businesses to seek professional legal advice.

An updated statement will be provided upon receipt of additional information.