8EHQ-0901-15014

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The Plastics Industry Trade Association

September 21, 2001

CONTAINS NO CONFIDENTIAL BUSINESS INFORMATION

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Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20406

8EHQ-01-15014

Re: Skin sensitization low molecular weight solid epoxy resins (bisphenol A–epichlorohydrin copolymers)

Dear Sir/Madam:

The following information is being submitted by The Society of the Plastics Industry, Inc. (SPI) pursuant to current guidance issued by the Environmental Protection Agency (EPA) indicating EPA's interpretation of section 8(e) of the Toxic Substances Control Act. SPI has made no determination as to whether a potential risk of injury to human health or the environment is actually presented by the findings.

A dermal sensitization study on a commercial sample of a low molecular weight "1 type" solid epoxy resin (average molecular weight of approximately 1000 variously described as CAS Nos 25068-38-6 or 25036-25-3) was sponsored by the Association of Plastics Manufacturers in Europe (APME) Epoxy Resins Committee (ERC) and conducted at RCC Ltd, Fullinsdorf, Switzerland. For an explanation of epoxy resin characteristics, see attached document entitled "Explanatory note on epoxy resin characteristics." The study was conducted in accordance with OECD Guideline No. 406 (specifically, the study conducted was the guinea pig maximization of Magnussen-Kligman with adjuvant) and in compliance with the Swiss Ordinance based on the OECD Principles of Good Laboratory Practice.

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In the first phase of the study, female albino guinea pigs received a challenge dose via dermal applications of 25% of the "1 type" solid Epoxy Resin in the test vehicle; 100% of the test animals showed skin effects, including patchy to moderate erythema, after 24 hours; patchy to intense erythema was reported after 48 hours. The control group did not show signs of skin effects. In the second phase of the study, similar effects were observed at the same time periods for dermal applications of 25% and 10% of the test material in the test vehicle.

Based on the laboratory's findings, these results were interpreted to indicate that a commercial bisphenol A based epoxy resin with an average molecular weight of approximately 1000 produced allergic contact dermatitis in guinea pigs. Since "1" type epoxy resins are known to contain up to 20% of unreacted monomer bisphenol A diglycidylether (CAS No 1675-54-3), a known skin sensitizing substance, and

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since lower molecular weight epoxy resins have previously been shown to produce skin sensitization, this result is not unexpected. Similar studies of higher molecular weight solid epoxy resins (average molecular weight > 1200) have not shown skin sensitization in guinea pigs.[1]

Please contact me if you have any questions or require further information.

Sincerely,

Lynne R. Harris
Executive Director
Epoxy Resin Systems Task Group

Attachment (1)

[1] See attached report table of findings

Explanatory note on epoxy resin characteristics:

This explanatory note serves to provide some basic knowledge about the characteristics of epoxy resins in view of a discussion about their classification and labeling.

Bisphenol A based epoxy resins are polymeric reaction products made from the monomers bisphenol A and epichlorohydrin. Depending on the mol ratio of these two monomers, the molecular weight of these polymers may vary from 340 (liquid epoxy resins) up to >30.000 (ultra high molecular weight epoxy resins, sometimes also referred to as phenoxy resins). The chemical structure of epoxy resins is described in figure 1 whereby **n** is the number of repeating units in the molecule.

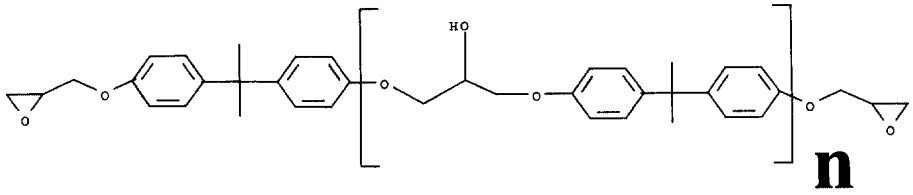

Figure 1: chemical structure of bisphenol A based epoxy resin homologues

The above structure describes individual epoxy resin molecules. Commercially available grades, however, always consist of mixtures of these homologues. They can be conveniently characterized by their so-called Epoxide Equivalent Weight (EEW), which is defined as "grams of resin containing one equivalent of epoxy groups" (expressed in grams/equivalent). The number average molecular weight number Mn of bisphenol A based epoxy resins ($= \Sigma N_i * M_i / \Sigma N_i$) can be derived from the EEW to a good approximation by simply multiplying the EEW number by 2.
Table 1 provides an overview of the different types of commercially available epoxy resins.

Table 1: overview of different types of commercially-available epoxy resins

Epoxy resin	n	EEW	Mol Weight (M_n)
Liquid epoxy resin	0	170	340
Semisolid epoxy resin	1	312	625
Low Molecular Weight solid epoxy resin	2-6	450-1000	900-2000
High molecular weight epoxy resin	10-30	1600-4500	3200-9000
Ultra high molecular weight epoxy resin	>50	>15.000	>30.000

Epoxy polymers typically show a Gaussian type of molecular weight distribution. This can be determined with Gel Permeation Chromatography (GPC). The number average molecular weight number M_n, the key parameter for the classification of epoxy resins, is not to be confused with the "weight average molecular weight number" M_w ($= \Sigma N_i * M_i^2 / \Sigma N_i * M_i$), which reflects the broadness of the molecular weight distribution and is usually much higher compared to the M_n number.

For example, a lower molecular weight epoxy resin with EEW= 500 would have an M_n number of 1000, whereas the weight average molecular weight M_w, as determined by GPC, would be typically around 2000-3000. It should be mentioned that depending on the calibration standard used in the GPC analysis, the real molecular weights might differ from the measured molecular weight. Also the type of detection technique used might have an effect on the measured molecular weight.

As a result of the natural molecular weight distribution, solid epoxy resins contain a certain fraction of epoxy oligomers with a MW (i.e. an M_n) <700 (n= 0 and 1) which can be measured either by Gel Permeation Chromatography (GPC) or High Pressure Liquid Chromatography (HPLC). As a rule of thumb, one can state that the higher the average molecular weight of the epoxy, the lower the level of epoxy species with MW<700. Table 2 provides a rough indication of the weight percentages of MW<700 species in commercial epoxy resins based on a limited dataset (industry typically does not analyze for MW<700 as it is not part of the routine quality control for epoxy resins).

Table 2: weight fraction MW<700 in solid epoxy resins

Type of solid epoxy resin	avg n	EEW	Mn number	% MW<700
"1" type epoxy	2	450	900	<30%
"2" type epoxy	3	600	1200	<20%
"4" type epoxy	5	900	1800	<10%
"7" type epoxy	10	1600	3200	<5%
"9" type epoxy	20	3000	6000	<4%