Hazard Risk Assessment from the Use of Polymer Clays

Polymer clays are made up of a mixture of polyvinyl chloride and a phthalate ester. Curing of the finished clay product requires heating at a controlled temperature (130-135°C or 265-275°F.). Potential exposures may occur from the accidental ingestion of the product, from skin contact during the production steps and during incidental food contact from materials released during baking. Over heating of polymer clays can result in breakdown of the clay with release of hydrogen chloride gas.

Toxicity Concerns
Phthalate esters used in polymer clays have a low order of acute toxicity with ingestion or skin contact with no lethalities occurring at maximum doses (up to >20 g/kg orally and >5 g/kg by skin contact). Testing for skin irritation and sensitization of these esters has been negative.

Phthalate esters used in polymer clays are metabolized to mono-phthalates in the intestine. The mono-phthalates act similar to fatty acids causing excessive triglyceride synthesis in the liver with high level dosing. Subacute or chronic dosing with these phthalates leads to mild liver changes one would see with ingestion of alcohol and a high fat diet. Acute high level or chronic dosing with some or these phthalate esters can cause testicular atrophy, decreases reproductive performance, and fetal effects at high doses. Genotoxicity of these phthalate esters and their metabolites has been negative.

The major route for absorption of these phthalate esters is by ingestion. Appreciable absorption via skin is unlikely. These phthalates are poorly absorbed through the skin with absorption rates ranging from 0.002 to 0.05% per hour.

Polyvinyl chloride polymers can contain residual levels on vinyl chloride (VC). High level, chronic exposures to vinyl chloride have caused damage to small blood vessels and Raynaud's disease in
workers as well as an increased risk of developing angiosarcoma of the liver and other tumors. Chronic dosing of VC to experimental animals results in effects on the liver and testes as well as a similar range of tumors seen in over-exposed workers. California has completed a risk assessment for VC under its Safe Drinking Water Act: a level of 3 micrograms per day would be protective for cancer effects.

When determining risk from exposure to polymer clays, a conservative assumption is that a user will ingest 100 mg of clay each day they are used, working 40 hours per week. We have surveyed artists who routinely use sculpting materials (including modeling clay) to determine actual frequency of use of such materials. In 1991 NFO Research conducted a national survey of artists. This survey was made by polling a 20,000 households representative of the US population. Nine percent of these households contained artists. A representative sample of 385 of these artists were asked detailed questions concerning their art work. 70% of those surveyed responded. The results are considered representative of the population of the United States with a precision of \( \pm 5.9\% \) at a 95% confidence interval. In this survey, the respondents were asked specifically how many hours they spend in each type of art work. Artists whose primary work was with sculpting materials used these materials an average of 9.6 hours/week. Our exposure assessment includes information from this survey.

**Potential risks from baking polymer clays**

The Consumer Product Safety Commission (CPSC) has extensively tested samples of polymer clay for safety concerns. Testing included analyses of clay extracts by gas chromatography/mass spectroscopy and analysis of gas release with heating. They found that the polymer clay tested did not contain any volatile organic compounds and that no acid gases were released if the clay was baked to 163\(^{\circ}\)C (325\(^{\circ}\)F). They found that hydrogen gas was released once the clay was heated to the point of turning black, 180\(^{\circ}\)C (356\(^{\circ}\)F).

The potential for incidental food contact with phthalate esters has been assessed both in laboratory and studio studies. Samples of polymer clay were heated continuously for 30 minutes in a tube furnace with any phthalates given off collected on an absorbent resin using a short path thermal collection system. The released esters were extracted using NIOSH Method 5020 and analyzed by gas chromatography. In order to judge how overheating may affect phthalate ester release, studies were performed not only at the recommended use temperature but at 165\(^{\circ}\)C and 190\(^{\circ}\)C, as well.

The results of the tube furnace studies were as follows:

<table>
<thead>
<tr>
<th>Operating Temperature (^{\circ})C</th>
<th>Phthalate Ester Release ((\mu)g/g) Clay Type I</th>
<th>Phthalate Ester Release ((\mu)g/g) Clay Type II</th>
</tr>
</thead>
<tbody>
<tr>
<td>135</td>
<td>18</td>
<td>7</td>
</tr>
<tr>
<td>165</td>
<td>202</td>
<td>129</td>
</tr>
</tbody>
</table>
These results were compared with a heavy use situation by wiping the interior of the oven and analyzing the resultant wipe as above. Over heating had occurred at least once. 57 μg/g of phthalate ester was released. It appears that routine use of an oven to cure polymer clays will result in little (<0.01%) loss of clay weight as esters. This level of exposure would add little to the base exposure presumption for these clays, even assuming concurrent use of the oven to bake foods.

To assess the potential for break down of the polymer matrix and release of irritating gases, samples were heated in an oven and hydrogen chloride gas release was monitored. For Clay Type I, no release occurred at temperatures below 180° C. (356 ° F.) in one experiment and below 200° C. (392° F.) in a second experiment. At higher temperatures there was release of HCl and blackening of the clay. For Clay Type II, there is <0.2% weight loss of the clay at baking temperatures of <200° C.

**Assessment of Health Risk Associated with the Use of Polymer Clays**

The phthalate ester content of polymer clays ranges from 10-25%. Di (2-ethylhexyl) phthalate is not used in polymer clays certified by the Art & Creative Materials Institute. One concern of exposure to phthalate esters found in polymer clays is reproductive effects or liver effects. Our risk assessment has been modified to include the recent findings of the National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction Expert Panel on Phthalate esters. Using a 100 fold uncertainty factor, incidental exposure from working with polymer clays would not be associated with any risk of developmental effects, reproductive difficulty or organ damage.

The vinyl chloride content of polymer clays is at non-detectable levels with a detection limit of 1 ppm or less. Using our exposure presumption, <0.1 micrograms of VC would be absorbed a day, a level associated with negligible risk.

Looking at thermal breakdown products of polymer clays, if all the weight loss at 200° C. was do to HCl release, and if 100 gm of clay were being baked, than up to 200 mg of HCl could be released. If this gas was further diluted in an average sized room of 30 m³, then the exposure level would be <7 mg/m³, a level that would not cause any effects.

In summary, phthalate esters found in these polymer clays offer little or no acute toxicity concerns and are not a chronic hazard concern even assuming a large (24 mg) daily ingestion of these clays. Analyses of these clays for residual vinyl chloride found non-detectable (<1 ppm) levels. The clay matrix does not break down to release hydrogen chloride gas until temperatures of 350° F. or greater are reached, with progressive release at higher temperatures: curing at temperatures low enough to prevent destruction and blackening of the clay body will prevent appreciable hydrogen gas release. Little phthalate ester is released during curing, even when heated to the point that the clay breaks down: there is little opportunity for incidental food contact.