**Macopharma DEHP-FREE blood bags**
show exceptional storage performances of blood components while reducing potential risks of DEHP exposure to patients.

**MACOPHARMA BLOOD BAGS PLASTICIZED WITH DINCH (DIISONONYLCYCLOHEXANE DICARBOXYLATE) OFFER EXCELLENT ALTERNATIVE TO DEHP PLASTICIZERS**

![Diagram of blood bags](image)

The European Directive 2007/47/EC advises to use alternatives to DEHP-PVC as far as possible. The plasticizer DINCH is an alternative to DEHP in the manufacturing of blood bags.

**DINCH** has a very low migration rate and an excellent toxicological profile:

- No testicular toxicity, nor impairment of fertility, nor teratogenicity;
- No carcinogenic potential.

**DINCH** satisfies the requirements of Council Directive 93/42/EEC (medical applications)

Hexamoll® DINCH® is the most eco-efficient non-phthalate plasticizer for PVC applications, with the lowest overall environmental impact.

It offers significant toxicological advantages over the complete life cycle, especially regarding consumer exposure.

Source: BASF
Macopharma performed a comparative study between DINCH and DEHP plasticized PVC for storage of red cell concentrate (in SAGM and PAGGSM) and plasma.

1- Parameters studied in red cell concentrates
- Red blood cells, Hemoglobin, Hematocrit
- Residual Leukocytes
- Residual Platelets
- pH, pO2 et pCO2
- Glucose
- Plasma Hemoglobin
- Potassium and Sodium
- LDH assay (U/l)
- ATP (μmol/g Hb)
- Lactate (mg/l)

Below are the parameters that are significantly different:

a) Hemolysis

b) pH

c) Lactate metabolism

d) Metabolic parameters
2- Parameters studied in plasma and results after 12 months of preservation

Results after 12 month storage

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DEHP Mean</th>
<th>DEHP SD</th>
<th>DINCH Mean</th>
<th>DINCH SD</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7.36</td>
<td>0.07</td>
<td>7.40</td>
<td>0.07</td>
<td>NS</td>
</tr>
<tr>
<td>K- (mEq/L)</td>
<td>3.87</td>
<td>0.38</td>
<td>3.79</td>
<td>0.27</td>
<td>NS</td>
</tr>
<tr>
<td>Proteins (g/L)</td>
<td>60.30</td>
<td>2.65</td>
<td>59.67</td>
<td>4.05</td>
<td>NS</td>
</tr>
<tr>
<td>Albumin (g/L)</td>
<td>37.91</td>
<td>1.39</td>
<td>37.58</td>
<td>2.03</td>
<td>NS</td>
</tr>
<tr>
<td>IgG (g/L)</td>
<td>8.18</td>
<td>1.36</td>
<td>8.30</td>
<td>2.53</td>
<td>NS</td>
</tr>
<tr>
<td>IgA (g/L)</td>
<td>1.75</td>
<td>0.72</td>
<td>1.84</td>
<td>0.69</td>
<td>NS</td>
</tr>
<tr>
<td>IgM (g/L)</td>
<td>1.11</td>
<td>0.35</td>
<td>1.10</td>
<td>0.29</td>
<td>NS</td>
</tr>
<tr>
<td>Cholesterol (g/L)</td>
<td>1.53</td>
<td>0.28</td>
<td>1.48</td>
<td>0.27</td>
<td>NS</td>
</tr>
<tr>
<td>Triglycerides (g/L)</td>
<td>0.97</td>
<td>0.52</td>
<td>0.97</td>
<td>0.52</td>
<td>NS</td>
</tr>
<tr>
<td>QF (%)</td>
<td>85.47</td>
<td>8.11</td>
<td>37.83</td>
<td>6.55</td>
<td>NS</td>
</tr>
<tr>
<td>ACT (s)</td>
<td>38.16</td>
<td>4.63</td>
<td>37.14</td>
<td>3.19</td>
<td>NS</td>
</tr>
<tr>
<td>Fibrinogen activity (g/L)</td>
<td>2.44</td>
<td>0.61</td>
<td>2.99</td>
<td>0.70</td>
<td>NS</td>
</tr>
</tbody>
</table>

MIGRATION OF PLASTICIZERS IN PLASMA

There is a lower migration of plasticizer into the plasma stored in PVC-DINCH containers.

<table>
<thead>
<tr>
<th>PLASTICIZER RATE (μg/g)</th>
<th>MEAN</th>
<th>MINI</th>
<th>MAXI</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEHP</td>
<td>17.4</td>
<td>14.6</td>
<td>19.9</td>
</tr>
<tr>
<td>DINCH</td>
<td>2.6</td>
<td>1.9</td>
<td>3.4</td>
</tr>
</tbody>
</table>

DINCH leaching in plasma is decreased by 85% compared to DEHP.
DINCH PLASTICIZER EXCEEDS STORAGE PERFORMANCE OF DEHP PLASTICIZER AT COLD TEMPERATURE

Macopharma performed drop tests with blood containers stored at cold temperature (3 – 4 °C) after (24h & 42 days) to compare DEHP-plasticized containers with DINCH-plasticized containers.

This study demonstrated a leakage reduction of 75 % with DINCH-plasticized containers.

PUBLICATIONS

- DEHP-free containers for collection, processing and storage of labile blood products, comparative evaluations of FFPs.
  Fontaine O, Melique S, Doolaeghe MC, Huart JJ, Goudaliez F, Verpoort T, Dekerle D, Poplineau J.
  Vox Sang. 2012;103(Suppl. 1), 1–271

- Screening study on hemolysis suppression effect of an alternative plasticizer for the development of a novel blood container made of polyvinyl chloride.