How to identify a substance on the borderline of a mono- and multi-constituent

Introduction

A substance is manufactured with concentration ranges of constituents that cross the thresholds of a mono- or multi-constituent substance.

Composition

The substance is manufactured with the following composition:

<table>
<thead>
<tr>
<th>Constituents</th>
<th>Concentration range (%)</th>
<th>Typical concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Case 1</td>
</tr>
<tr>
<td>Zolimidine</td>
<td>74 - 86</td>
<td>77</td>
</tr>
<tr>
<td>Imidazole</td>
<td>4 – 12</td>
<td>11</td>
</tr>
<tr>
<td>Impurity A</td>
<td>0 - 8</td>
<td>7</td>
</tr>
<tr>
<td>Impurity B</td>
<td>0 - 6</td>
<td>5</td>
</tr>
</tbody>
</table>

Identification

In general, a substance is a mono-constituent substance, if one constituent is present at a concentration of \( \geq 80 \% \). A substance is a multi-constituent substance, if more than one constituent is present at a concentration \( \geq 10 \% \) and \( < 80 \% \).

In this case, the concentration ranges of the two major constituents cross both the 10 % and 80 % thresholds. Therefore, the substance can be identified as either a mono- or a multi-constituent substance.

In such borderline cases, it is the typical concentration values of the constituents in the substance, which determine the substance type and naming.
• **Case 1:**

  The typical concentrations of both Zolimidine (77 %) and Imidazole (11 %) are ≥ 10% and < 80%.

  Therefore, the substance is a multi-constituent substance named as a reaction mass of its main constituents (≥ 10 %): “Reaction mass of zolimidine and imidazole”

• **Case 2:**

  The typical concentration of Zolimidine (85 %) is ≥ 80 %, while Imidazole is only present as an impurity (5 %).

  Therefore, the substance is a mono-constituent substance named after its main constituent (≥ 80 %): “Zolimidine”

As the two compositions would result in two different names and substance types then two separate registrations would be required. One registration for the mono-constituent substance and one registration for the multi-constituent substance.