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## 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:

Constituents	Concentration range (%)	Typical concentration (%)	
		Case 1	Case 2
Zolimidine	74 - 86	77	85
Imidazole	4 - 12	11	5
Impurity A	0 - 8	7	6
Impurity B	0 - 6	5	4

### 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.

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- **Case 1:**

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

Therefore, the substance is a multi-constituent substance named as a reaction mass of its main constituents ( $\geq 10\%$ ): "Reaction mass of zolimidine and imidazole"

- **Case 2:**

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

Therefore, the substance is a mono-constituent substance named after its main constituent ( $\geq 80\%$ ): "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.