

Type of Document
IM 2014-25
Date
04 November 2014
From
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Distribution		Regarding	
To whom it may concern		Statement – Admixing properties of Addaven.	
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Addaven is a new multi-trace element product that is an updated product based on the current Addamel N.

The composition of Addamel N has been updated to reflect new clinical recommendations (see Table 1). The concentration of three of the nine trace elements has been decreased (Cu, Zn and Mn) and the concentration of one trace element has been increased (Se).

Apart from the adjustment of the concentration of some of the trace elements, the product remains the same. No changes were made to the manufacturing process, nor the container closure system (PP ampoule). The two products thus have the same physico-chemical properties and are pharmaceutically equal. Therefore, the results from compatibility studies with Addamel N are not expected to differ depending on which one of the two products that are used as trace element source.

Tests performed show that Addaven, the novel produced multi-trace element product, is stable and compatible with all tested admixtures and has therewith proven to possess appropriate admixing properties. The results of these studies show that the small difference in composition between the pharmaceutically equal products Addamel N and Addaven does not affect the admixing properties of the products. The available compatibility data on Addamel N is therefore also valid for Addaven

Table 1. Addamel N and Addaven composition in mg and μmol per ml

	Addamel N		Addaven	
	Iron, Fe^{3+}	2.0 μmol	110 μg	2.0 μmol
Zinc, Zn^{2+}	10 μmol	650 μg	7.7 μmol	500 μg
Manganese, Mn^{2+}	0.5 μmol	27 μg	0.10 μmol	5.5 μg
Copper, Cu^{2+}	2.0 μmol	130 μg	0.60 μmol	38 μg
Selenite, SeO_3^{2-}	0.040 μmol (as Se^{4+})	3.2 μg (as Se^{4+})	0.10 μmol (as Se^{4+})	7.9 μg (as Se^{4+})
Molybdate, MoO_4^{2-}	0.020 μmol (as Mo^{6+})	1.9 μg (as Mo^{6+})	0.020 μmol (as Mo^{6+})	1.9 μg (as Mo^{6+})
Iodine, I^-	0.10 μmol	13 μg	0.10 μmol	13 μg
Chromium, Cr^{3+}	0.020 μmol	1.0 μg	0.020 μmol	1.0 μg
Fluorine, F^-	5.0 μmol	95 μg	5.0 μmol	95 μg

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A handwritten signature in black ink, appearing to read "M. Willuhn", written over a horizontal line.

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