Introduction and Purpose
Food and fluid consumption can significantly alter drug dissolution in the upper gastrointestinal tract. Whereas over the last decades the intraluminal fluid composition in the fasted or fed gastrointestinal tract of adults has been screened and was translated into biorelevant in-vitro test designs, there is not much known about the intraluminal conditions relevant to dissolution in the paediatric gastrointestinal tract.

The present study focused on obtaining information on typical food and fluid compositions and volumes consumed by children in the age of 1 – 6 years with the aim of developing biorelevant dissolution methods for orally administered drugs in this age categories.

Experimental Methods
A survey was conducted to examine fluid and food consumption in German infants and pre-school children. Parents were asked to record fluid volumes and composition as well as the qualitative and quantitative meal composition ingested by the child over a total of four days. The survey was distributed in nursery schools in different parts of Germany (see Fig. 1) and could also be passed to other parents. The resulting data were grouped according to the age of the child.

Since a majority of oral dosage forms is administered in the morning the focus of the present part of the study was set at evaluating the qualitative and quantitative composition of the breakfast and co-administered fluids. To get an idea of trends in eating habits, the meals were divided into their single components which were successively assigned to major food groups, like it was similarly done in previous studies on the eating habits in children [1]. For each child and each day every single component of each meal was registered. Subsequently, the relative frequency of consuming this single component was calculated by relating the observed frequency for the respective component to the total number of single components obtained by this recording procedure.

Results
97 completed questionnaires could be evaluated. The age of the children whose meals were documented are quite evenly distributed (see Fig. 2). Most of the questionnaires were documented in Mecklenburg-West Pomerania and Rhineland-Palatinate (see Fig. 3).

Unexpectedly, among the different age classes, the preferences for most of the meals were quite similar. The favourite meals for breakfast were several kinds of bread, which were buttered and/or spread with a sweet topping (see figure 4, data are shown in more detail in figures 6 and 7). Other meals often mentioned were fruits, breakfast cereals (Fig. 8) or dairy foods. Overall, even for infants, the qualitative composition of the breakfast was similar to that of older children or adults. The favourite drinks were whole milk, cocoa or other dairy beverages like formula milk for infants or flavoured dairy products like vanilla milk.

Fig. 2 Age distribution of the children

Fig. 3 Distribution of the geographical localization in Germany

Fig. 4 Typical breakfast ingredients consumed by German infants and pre-school children

Fig. 5 Typical beverages consumed at breakfast by German infants and pre-school children

Fig. 6 Different toppings on bread consumed by children

Fig. 7 Different kinds of bread consumed by children

Fig. 8 Ingredients of breakfast cereals consumed by children

Conclusion
Data obtained in the present study give an important insight into paediatric eating and drinking habits at breakfast time. The documented meals, fluid compositions and volumes will help to develop biorelevant dissolution methods for paediatric drug formulations.

References