

DETERGENT CAPSULES “ACCIDENTOLOGY” PROJECT FINAL REPORT

November 2, 2015

Executive Summary

To better understand the causal factors for accidental exposures to detergent capsules, A.I.S.E. partnered with five Poison Control Centres across Europe to conduct a prospective ‘accidentology’ research study. The scope covered all detergent capsules (laundry, dishwasher, and others) contained in a water-soluble film. Over a 6-month period, starting in autumn 2014, data on 401 cases were collected. Most exposures (82%) were to liquid laundry capsules, while 16% of the cases were with automatic dishwashing (ADW) capsules.

Children aged 12-24 months were most involved, especially for ingestion (which was by far the most frequent route of exposure). Nearly all incidents happened at home, in the room where the detergent products are used or stored.

Of all exposures where this information was reported, 66% of the cases were with capsules or packs that had either been directly accessible to the child, i.e. not in a pack (33%), or that had been in a pack that was not safely stored (also 33%). In 26% of all cases where the relevant information was available, the child had opened the original pack to get access to the capsule. Combined, this represents 44% of the accidents (where sufficient details are known) where the child had taken a capsule from a container.

For laundry capsules, Stand-Up Pouches have not been involved in more incidents compared to their market presence than plastic tubs. Also, no meaningful differences were observed between the number of incidents for capsules with different colours compared to their respective market presence.

77% of the exposures to laundry capsules were symptomatic. Mostly minor symptoms were reported (67%). Vomiting was the most prominently reported symptom, following 62% of the ingestion cases. All eye exposures were symptomatic and mostly led to eye irritation or inflammation. 10% of the accidental exposures led to moderate symptoms (PSS=2), especially cases with multiple routes of exposure.

Of the ADW cases, 58% were asymptomatic and 36% led to minor symptoms (mainly vomiting: 25%). There was one case with moderate symptoms (1.6%). Hence, ADW exposures were not only five times less frequent, but in addition the percentage of symptomatic cases was half of that with laundry capsules. This highlights the more favourable safety profile of the ADW capsule category (in line with the findings presented in 2014 by the Niguarda PCC).

The Poison Control Centres recommend to improve the child-impeding properties of the packaging for the products of concern; to sustain the consumer education efforts around safe use; and to further investigate factors that may drive the child-attractiveness of capsules, in order to reduce this attractiveness.



Background

To evaluate and, if needed, improve the effectiveness of the risk mitigation measures introduced through A.I.S.E.'s Product Stewardship Programme (PSP) for Liquid Laundry Detergent Capsules at the end of 2012, a better understanding of accident circumstances is required. To this end, A.I.S.E. has established the "Accidentology" project, a collaboration with five Poison Control Centres (PCCs) across Europe: Dublin (IE), Göttingen (DE), Milan (IT), Prague (CZ), and Utrecht (NL), serving a combined population of approximately 90 million inhabitants.

The study protocol (Appendix 5 to this report) was developed jointly by A.I.S.E. and the participating PCCs, mid 2014. Ethical reviews were conducted in each of the PCCs during summer 2014. The 6-month data collection phase took place in the last quarter of 2014 and the first quarter of 2015.

This report assesses and interprets the data collected about accidental exposure cases with detergent capsules during the Accidentology project.

Accidentology data set

Accident circumstances data were collected by 5 PCCs, over a 6-month period, starting in Fall 2014. Within scope were all unit dose detergent products contained in a soluble film: laundry, automatic dishwashing (ADW), and cleaners; either entirely liquid, or partially liquid / partially solid, or entirely solid.

Overview

In total, 430 cases were initially reported. However, 29 cases related to automatic dishwashing tablets that were likely not soluble film products, but rather, tablets in a disposable wrapper. As the scope of this project explicitly excludes such products, these 29 cases were removed from the data set - leaving 401 valid cases in total (Table 1):

Table 1. Overview of accident circumstances data set.

PCC	Estimated nr. of inhabitants covered	From	To	Reported (valid) cases			
				Total	Laundry	ADW	Cleaning
Dublin	4.6 million	6/10/2014	5/4/2015	28	27	1	0
Göttingen	13.0 million	1/10/2014	31/3/2015	23	17	6	0
Milan	45.0 million	1/11/2014	30/4/2015	150	113	34	3
Prague	10.5 million	1/10/2014	31/3/2015	99	88	11	0
Utrecht	16.9 million	1/10/2014	31/3/2015	101	84	12	5
TOTAL	90 million			401	329	64	8

Most cases (82% [329/401]) were with laundry capsules. Further, 16% [64/401] of cases with soluble film ADW products were reported, which is less than one fifth of the number of laundry exposures. Incidents with other soluble film detergent products (cleaners) were reported only sporadically (2% [8/401]) (Figure 1).

As laundry capsules and ADW capsules have different use patterns, a different history, a different chemical composition, and a different product form, the assessment of product-specific accidentology aspects of both product categories is presented in two separate sections in this report. For other product types (i.e. cleaning product capsules), the number of reported incidents was very limited, and furthermore limited to two out of the five studied countries. As such, it was judged not relevant to conduct a further assessment regarding product specific aspects on these data.

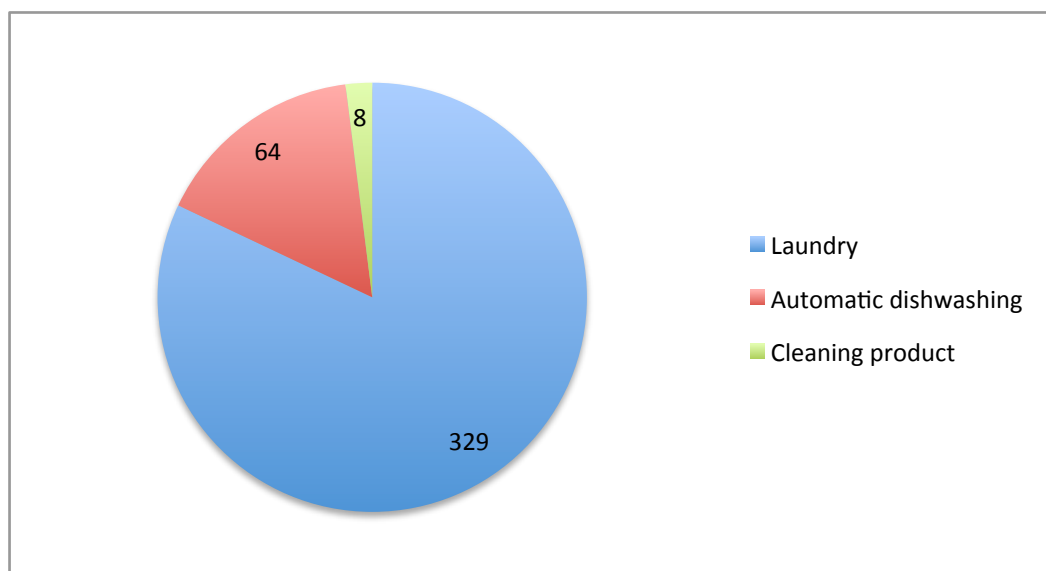


Figure 1. Accidentology data set: overview of product categories.

Limitations of the data set and data modifications

Representativeness

It must be noted that the data collected in this project are representative only of situations where (1) an incident occurred, (2) this incident was subsequently reported to a PCC, and (3) the reporting parent or medical professional was willing and able to collaborate with the study. We have no information whether the circumstances for these reported accidents may or may not be equivalent to the circumstances in case no PCC enquiry was made.

An assessment of the available data for cases where accidentology follow-up was not possible is presented in Appendix 4.

Modifications of the reported capsule form for ADW cases

The study protocol and the questionnaire template provided three options for the capsule form: either “entirely liquid”, or “part liquid / part solid”, or “entirely solid (powder tablet)”. These descriptions had overlooked one specific product form: an entirely solid tablet that consists of compressed powder combined with solid gel. This product is entirely solid according to the applicable definitions. However, in 5 cases it was reported as “part liquid, part solid” (because indeed it is not a “powder tablet”). As there was 100% certainty about the product identity for these 5 cases, the product form was modified to “entirely solid”.

Further, for all other cases where the product form had been reported as “entirely solid (powder tablet)”, this was reworded to simply “entirely solid”.

Modifications / exclusions of the reported capsule colour

For laundry capsules, the capsule colours were investigated in detail, relative to the market shares of the different colours. For 37 laundry incident cases, this assessment pointed to inconsistencies between the reported capsule colour and the reported brand name; or it was found that the reported colour did not exist in that market. Consequently, these cases were not further taken into account for the colour assessment.

For 10 cases with a specific single-colour two-compartment laundry capsule brand, the brand identification and the colour reporting was unambiguous - however, the colour had been reported as ‘Multiple Colours’. This was modified in the database.

These modifications are further explained in Appendix 2.

Packaging transparency

Due to their near complete absence from the market, cases with transparent laundry packs were reported only very rarely. The exception is the Prague PCC, which reported 11 cases with transparent laundry packs during the first month of the data collection (October), versus only one such case in the five subsequent months. The PCC confirmed that during the first month of data collection, “transparent packaging” could have been confused with “transparent capsules” (the same word in Czech - "obal" - can have both meanings). Consequently, the data on pack transparency for Prague in October is likely not valid, and was not used for the assessment and interpretation regarding this specific aspect.

Capsule “ready to use” and “not in container”

The question “Was product ready for use (i.e. already taken out of pack) when accident happened?” aimed to differentiate between cases where the capsule was stored in a container (and hence, the child had to take it out) or whether it was outside of a container (directly available). For several cases, the additional description unambiguously indicated that the capsule had been already outside of the container prior to access by the child; yet to the above questions the reported answer was “No”. This was seen especially for exposures to misplaced or lost capsules - where indeed the wording of the question may have been confusing. These responses (21 cases) were modified to correctly reflect that the capsule had been outside of a container prior to accidental access.

Statistical Assessments

Whereas the total number of reported cases is substantial, the sample sizes become very limited when investigating specific (combinations of) circumstances, product attributes, etc. As such, it was decided to not include an assessment of statistical significance for the reported observations. However, for transparency, for all reported comparisons the respective sample sizes are reported next to the calculated percentages.

Common assessment for all soluble film detergent capsules

This section covers accidentology aspects that are relevant across product categories. It is based on all valid collected data, on laundry, automatic dishwashing and cleaning products.

Identification of the patients

Gender

The number of incidents with males (49.9% [200/401]) was essentially the same as with females (50.1% [201/401]). From this, one may conclude that any differences in typical behaviour between male or female children, did not influence the risk.

Age

Over half of the incidents (51% [204/401]) occurred with children less than 2 years old, and 74% [298/401] with children aged less than 3.

Children typically go through an oral mouthing stage as infants¹, and will often bite and chew hands, blankets, books, toys, and anything in their immediate environment. The normal oral mouthing phase can last from birth through about age 18-24 months. This is in line with the clear peak of incidents in the age group of 1-year olds (46% [183/401] of the cases). Note that for children less than 1 year old, the number of incidents was substantially lower. This can be explained by the fact that most children within this age group are insufficiently mobile and have insufficient dexterity to be able to effectively put themselves at risk for exposure.

With increasing age, the number of exposures drops substantially, although 3- and 4-year olds were still relevant, involved in 18% [74/401] of the cases. This is shown in Figure 2.

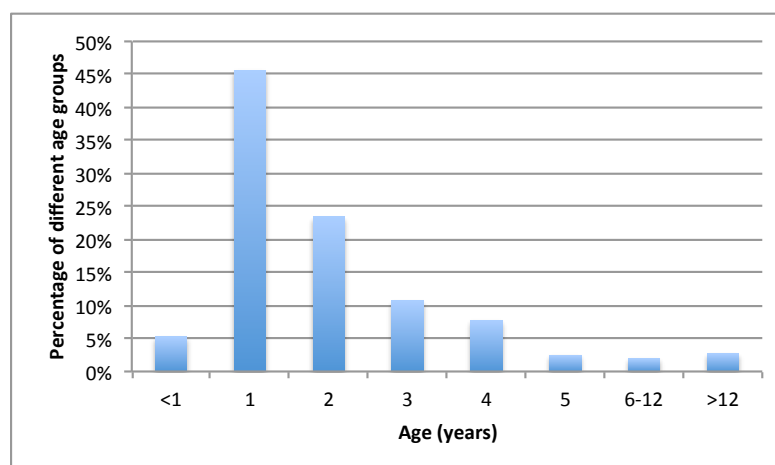


Figure 2. Incident frequency for different ages.

The age distribution was also investigated for cases where the children themselves opened the (original and properly closed) detergent capsules pack, in order to gain access to the product. The age distribution for these cases is nearly identical to the overall distribution, as can be seen in the red bars of Figure 3. In other words, there is no indication that children who opened the packs themselves to gain access to the capsules, were an older sub-population.

¹ e.g. Tulve N.S., McCurdy Suggs J.C., T., Cohen Hubal E.A. and Moya J. (2002). Frequency of mouthing behavior in young children. *Journal of Exposure Analysis and Environmental Epidemiology*, 2002, 12(4), 259-264.

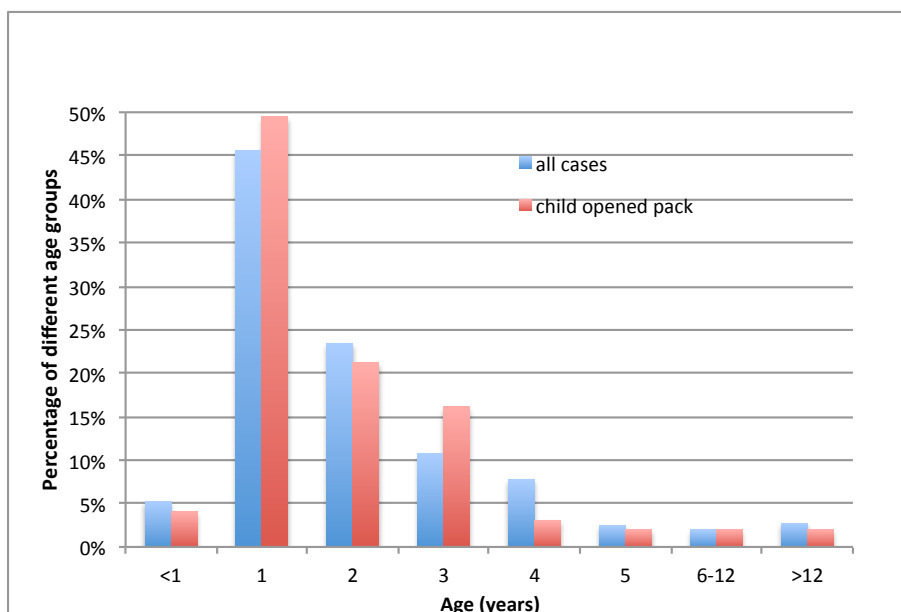


Figure 3. Incident frequency for different ages - cases where the child opened the pack.

For cases without ingestion (i.e. exposure to skin and/or eye, but without ingestion), the age distribution was different (Figure 4), with the highest frequency for the 24-36 month old children, and clearly less non-oral exposures for children less than 24 months old (11% [3/28] in this age group without ingestion, versus 60% [222/373] with ingestion).

This observation is in line with the hypothesis that the oral stage is an important factor for ingestion incidents, but not for incidents without oral exposure. Indeed, the children in the oral stage age group are less prominently represented for the non-oral exposures.

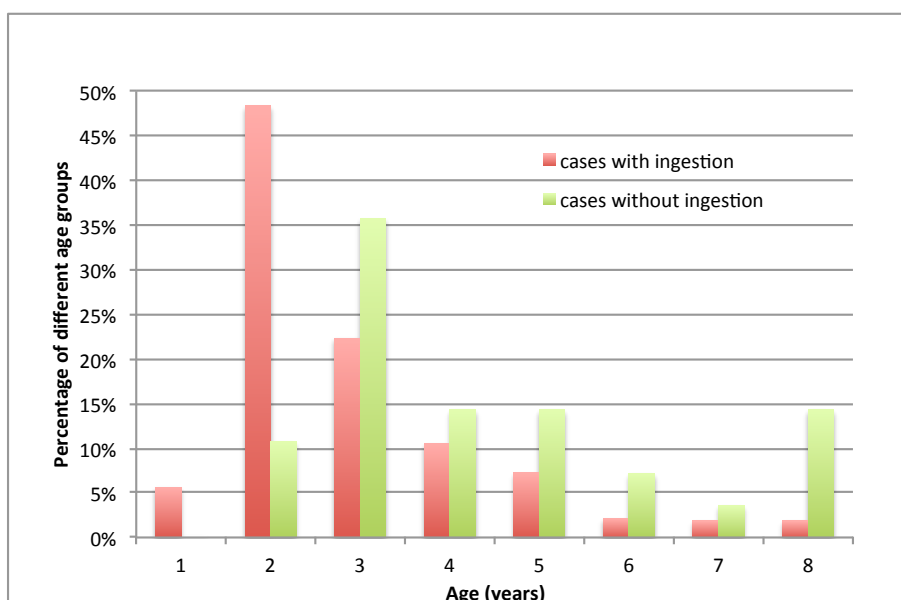


Figure 4. Incident frequency for different ages - oral versus non-oral exposures.

There was no apparent difference in the age distribution for incidents with automatic dishwashing capsules versus the distribution for cases with laundry capsules (Figure 5). It should be noted that any differences in the histogram for ADW may be related to the limited number of reported cases.

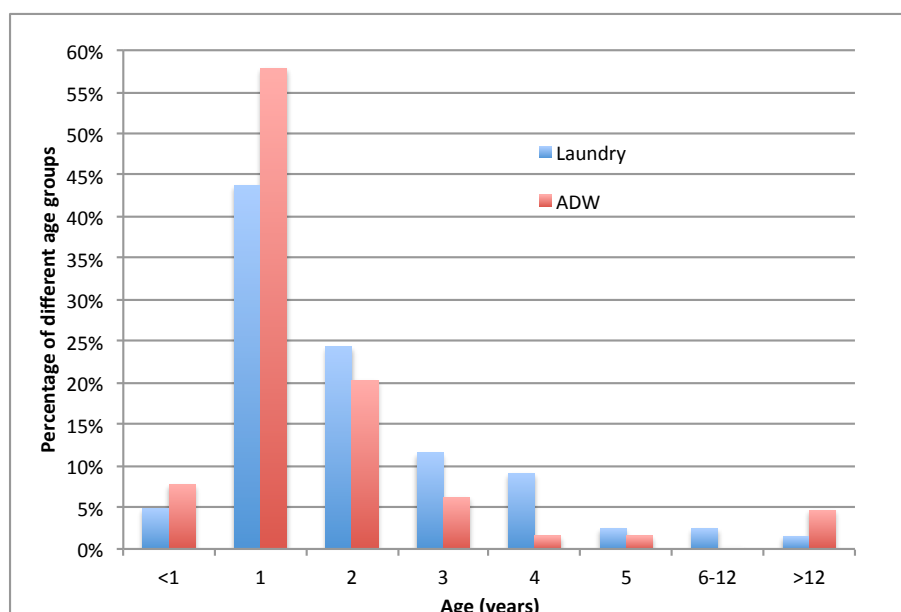


Figure 5. Incident frequency for different ages - laundry versus ADW cases.

Family situation: number of children

For cases where the family size was known, 40% [105/260] of the incidents happened in a single-child family. 44% [115/260] of exposures happened in families with two children, and the remaining 14% [40/260] in larger families.

This was compared to the average family sizes in Europe (for families with at least one child)² (Figure 6). This shows that incidents in families with one child seem to be over-represented versus the total number of such families (by a factor 1.6). On the other hand, for families with two or more children, there are less reported incidents proportional to the number of these families.

This observation is in line with the PCCs' general experience³ that poisoning incidents tend to happen somewhat more frequently with first-time parents, who have yet to learn in practice what are their child's abilities.

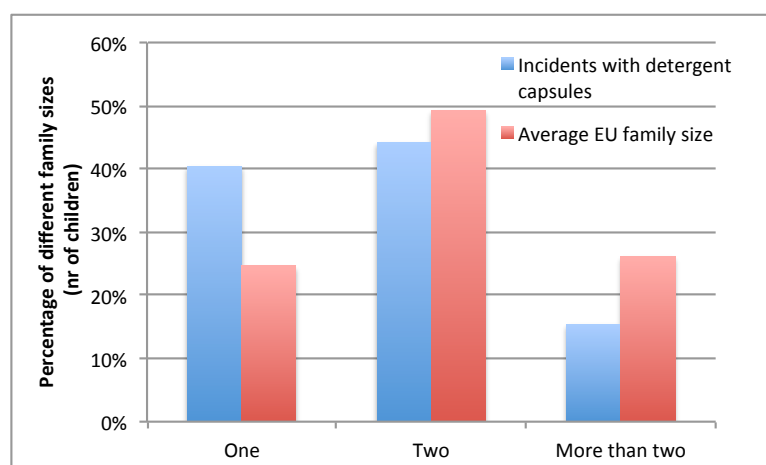


Figure 6. Family size: cases of incidents versus European average.

² Testa, Maria Rita. 2012. Family Sizes in Europe: Evidence from the 2011 Eurobarometer Survey". European Demographic Research Papers 2. Vienna: Vienna Institute of Demography. http://www.oeaw.ac.at/vid/download/edrp_2_2012.pdf.

³ Personal communication (15/9/2015) by the PCCs of Dublin, Göttingen, Milan and Utrecht.

Occurrence of the incidents

Day and Time

The incidents occurred largely at the same frequency across all days of the week (Figure 7).

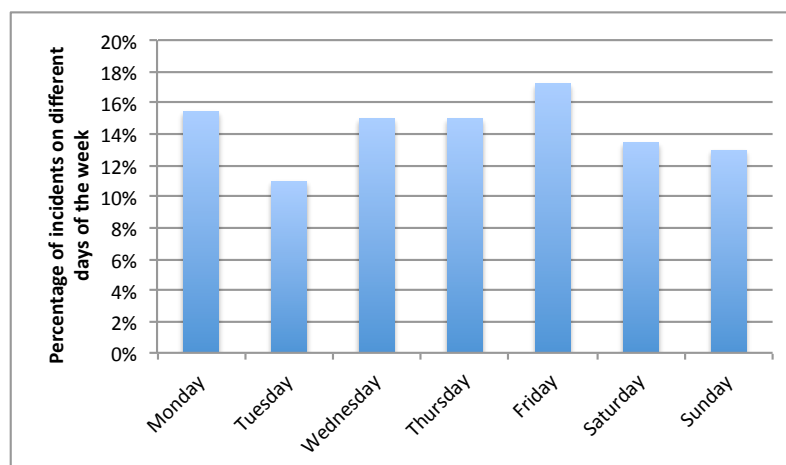


Figure 7. Incident frequency for different days of the week.

Across the different hours of the day, there was a slightly higher incident frequency in the late morning and again in the late afternoon / early evening (Figure 8). Fewer incidents seem to occur in the earlier morning and later in the evening, as well as, to a lesser extent, in the early afternoon. No incidents happened after midnight.

This observation is in line with the PCCs' general experience⁴ that poisoning incidents tend to happen and be reported somewhat more frequently around lunch time and again before supper.

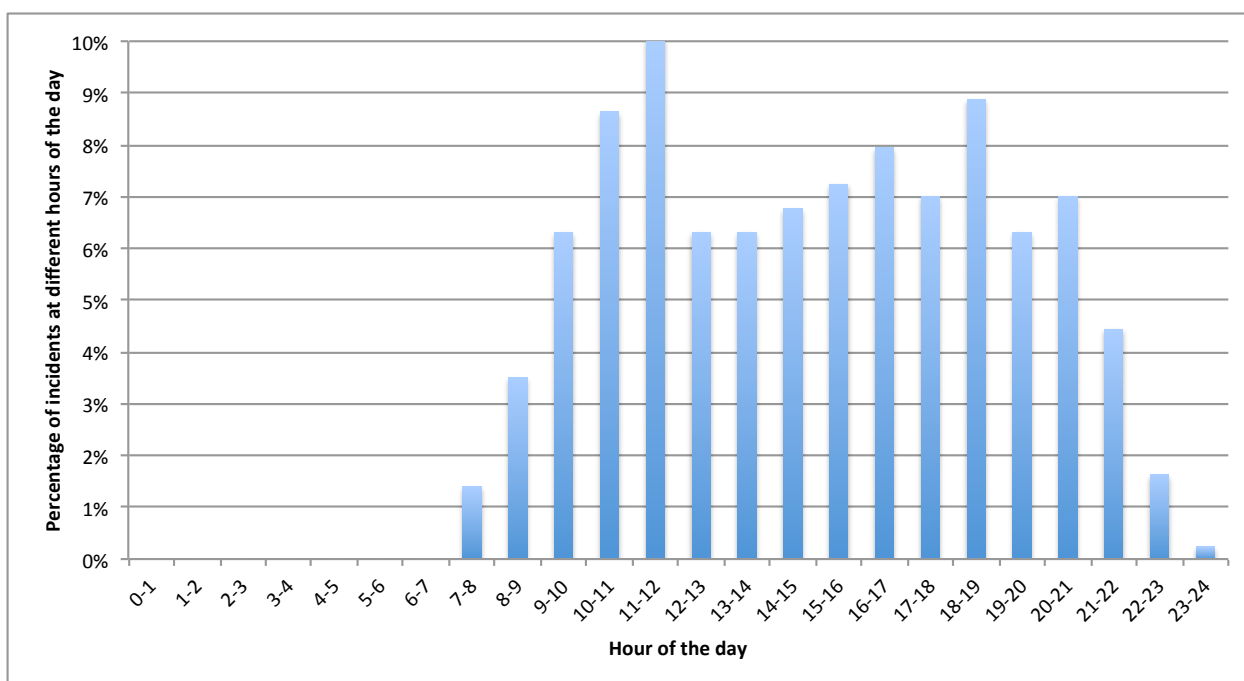


Figure 8. Incident frequency for different hours of the day.

⁴ Personal communication (15/9/2015) by the PCCs of Dublin, Göttingen, Milan and Utrecht.

Location

Nearly all incidents (96% [386/401]) took place at home. The remainder happened mainly at the homes of grandparents (2% [8/401]). No incidents were reported that happened at school or at a day care facility.

In the home, the incidents happened almost exclusively in those areas where the detergent capsule product is used and/or stored (i.e. the laundry room, the kitchen, or the bathroom) (Figure 9). Understandably, a key difference is seen between laundry and dishwashing capsules, driven by where the respective machines are located. Only very rarely (1% of the cases [4/401]), children took the capsules into their own room or the playroom.

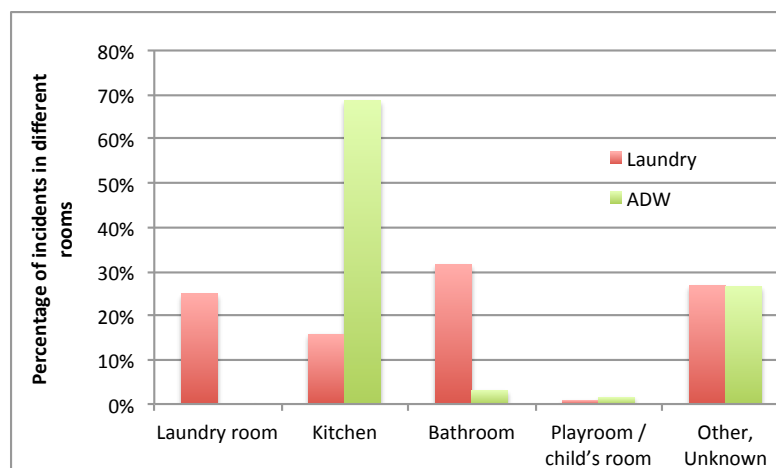


Figure 9. Incident frequency for different rooms in the home.

As to where in the home the incident happened, there was a major difference between countries for laundry, due to different locations of the washing machine, as illustrated in Figure 10. The findings are in line with national habits, namely the fact that in Ireland the washing machine is often located in the kitchen, while in Italy or the Czech Republic it is usually in the bathroom; and in the Netherlands and Germany a laundry room is more common. For ADW on the other hand, the dishwasher is commonly located in the kitchen in all countries, and this is also reflected in the accident location (Figure 11).

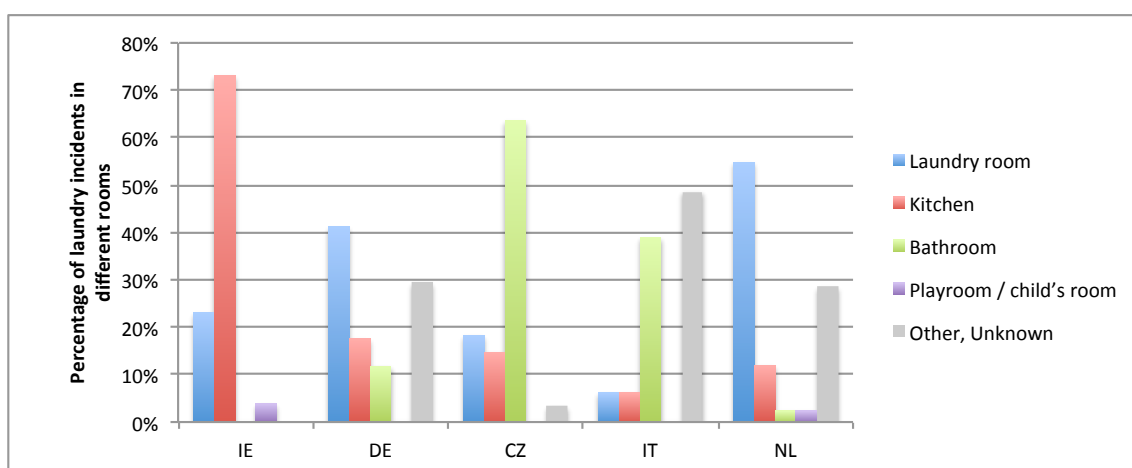


Figure 10. Incident frequency for different rooms in the home for different countries (laundry).

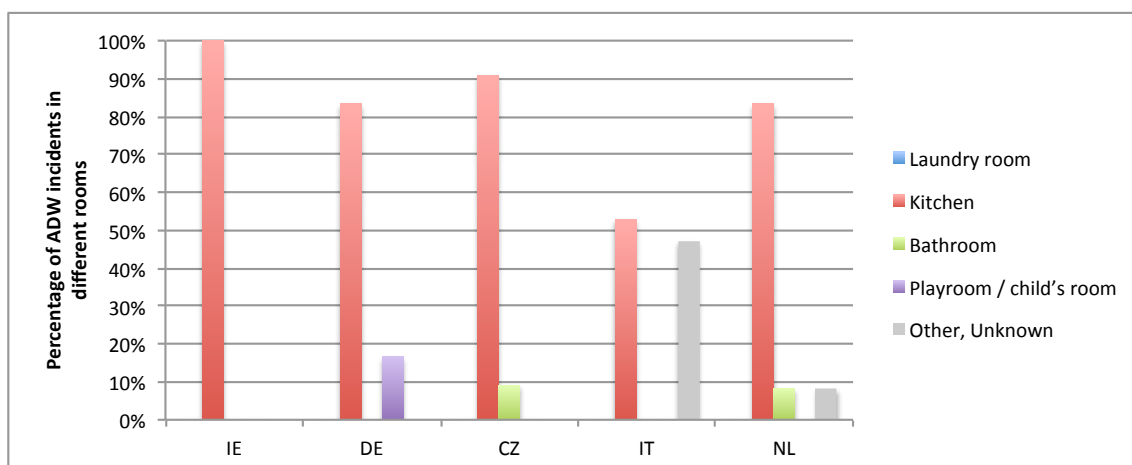


Figure 11. Incident frequency for different rooms in the home for different countries (ADW).

Access to the products

Access to the products depends on use and storage habits, and hence, is different for laundry versus ADW capsules. Consequently this aspect is elaborated in further detail in the subsequent sections of this report. However, there are similarities regarding direct accessibility of individual capsules, and regarding safe storage of the containers. Hence, an aggregated overview is also presented here.

Information whether the capsule had still been in a container or whether it had been already out of the packaging when the incident happened, is available for 76% of the cases [305/401].

When this information was known, in 33% [102/305] of the accidental exposures the detergent capsule had been already outside of the container.

In the other 67% [203/305] of the cases where this was known, it was reported that the capsule had been in a container:

- Of these containers, 26% [52/203] had been stored in a way deemed to be safely out of children's reach. 19% [38/203] were in a high cabinet or shelf - of which 3 times also with a child safe lock. 7% [14/203] were in a low cabinet that was secured with a child safe lock.
- On the other hand, in 49% [100/203] of the exposures it was reported that the storage had not been child-safe. Most commonly, the pack had been readily accessible e.g. on the kitchen counter or on the floor (36% [74/203]). Alternatively, the pack had been in a low cabinet without a child safe lock (13% [26/203]). In the remaining 25% [51/203] the exact storage location was unknown, but it was reported explicitly that there had been no specific child safety measures.

Across all 305 reported exposures where the relevant information was available, situations where the child took a capsule from a container that had not been stored in a child-safe way represent 33% [100/305] of the incidents.

Of all exposures where the relevant information was available (i.e. irrespective of whether the capsule had been in a container before the incident), in 26% [78/305] the child had opened the original packaging to gain access to the capsule.

Of the exposures where the capsule had been taken out of a container by the child, where known (179 cases), this had been from the closed original packaging in 44% [78/179] of the cases.

Laundry Detergent Capsules

Product form

Nearly all laundry cases (98% [322/329]) were reported to be with entirely liquid product. One case was with a part liquid, part solid capsule. For 6 cases (<2% [6/329]) the form was unknown.

Access to the products

An overview of circumstances leading to product access is shown in Figure 12. For 78% [255/329] of the laundry cases, information was available whether the capsule had been in a container when the accident happened. The further assessment focuses on these cases with known information.

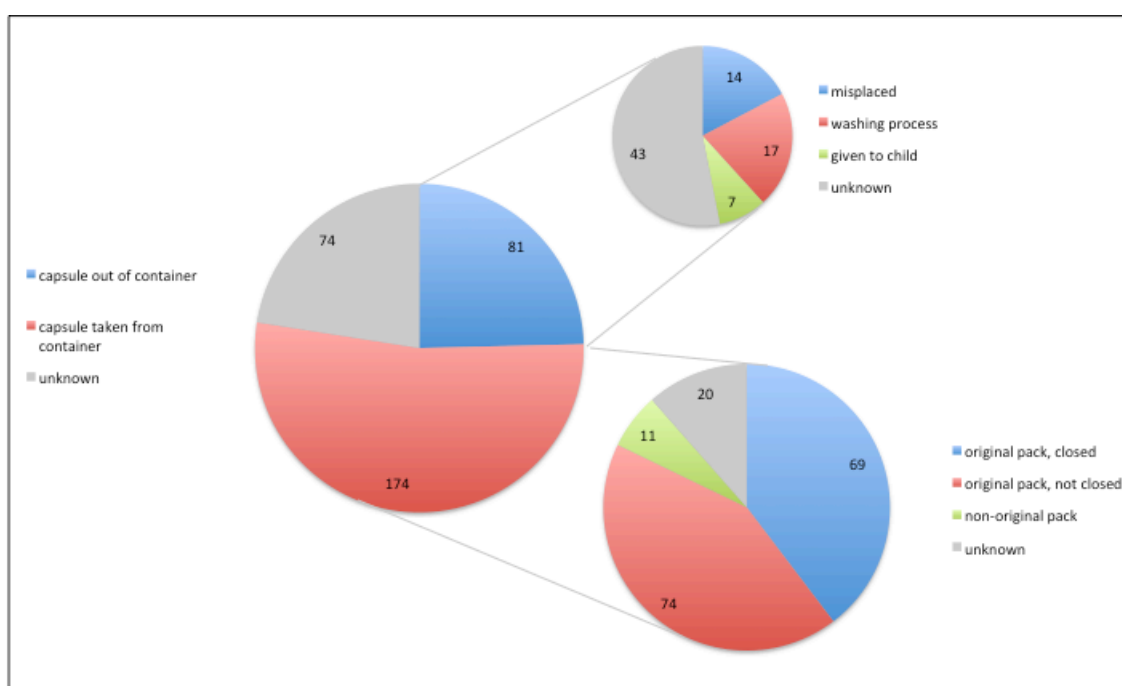


Figure 12. Access to laundry capsules - overview.

Cases where the child had direct access to the capsule

In 32% [81/255] of the incidents with laundry products, the capsule was not in a container when the incident happened⁵. For 47% [38/81] of these cases, more detailed information is available about the exact circumstances. Most frequently (45% [17/38]), the exposure happened during the preparation of the laundry process, when the child was able to take the capsule e.g. from the laundry basket or from the (open) machine. In 37% [14/38] of these cases with information, the child had found a capsule that had been lost, misplaced, or left somewhere out of its container (e.g. that had been dropped on the floor, or left on the kitchen counter). Finally in 18% of these exposures with known circumstances [7/38], it was reported the child had been given the capsule by the parent, either to put it into the machine (6 cases), or as a toy (1 case). It should be noted that the number of cases for which this type of information is available is fairly limited; hence, the findings should not be treated as quantitatively conclusive.

Cases where the child took the capsule from a container

In 68% [174/255] of the laundry cases with this information known, it was reported that the capsule had been in a container before the incident happened - i.e. that the capsule had not yet been taken out of the pack. In 89% [154/174] of these cases, more information was available. In 45% [69/154] of such cases, the capsules had been stored in their original packaging and this had been properly closed. This implies that the child opened

⁵ The impact on these findings of the corrections made to the originally reported data is assessed in App. 3.

the pack to get access to the capsule. In 48% [74/154] of such cases, the capsules had been in the original pack, but this had not been (properly) closed. As such, the pack closure was not a barrier. Finally, another 7% [11/154] of cases occurred with product that had been stored in a non-original container.

Child-safe storage

Only in 25% [44/174] of the cases where the product had not been already out of the pack, the products had been stored in a safe way (i.e. a high shelf or cabinet, and/or a cabinet secured by a child-safe lock). This represents 13% [44/329] of all reported laundry cases combined.

In 51% of these situations [89/174], on the other hand, the packs had not been stored safely. Either they were in a cabinet under the sink without child-safe lock (10% [18/174]), or more frequently, directly in the area where they were to be used, without any precautionary measures (e.g. on the floor, on the kitchen counter, on the washing machine) (41% [71/174]). For 24% [41/174] the exact storage location was not known but it was reported that no child safety had been put in place. This is illustrated in Figure 13.

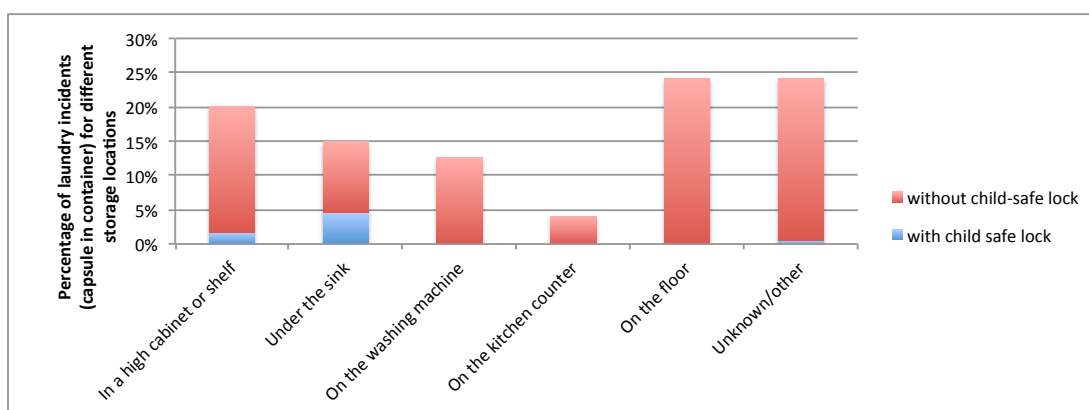


Figure 13. Storage location of laundry detergent capsule packs, for incidents where the capsule had been in a container.

Packaging Type

Incident frequency for different packaging types

85% [278/329] of the incidents with laundry capsules happened with product in plastic tubs, and 5% [17/329] in stand-up pouches (SUP) (Figure 14). Based on the brand name, the two cases in a carton box likely refer to non-original packaging.

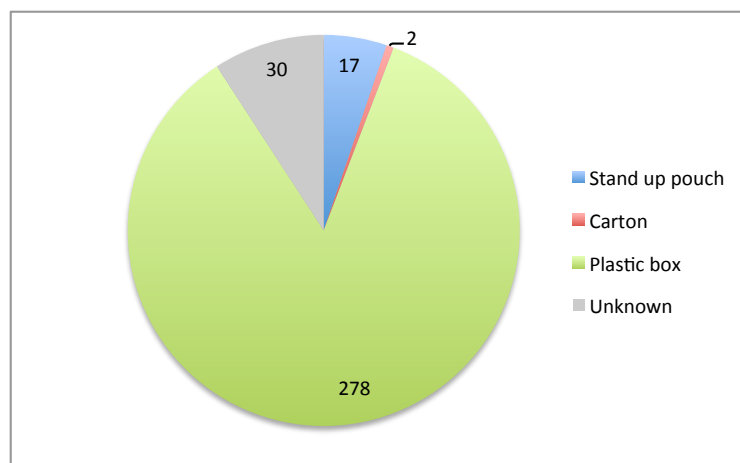


Figure 14. Incident count for different packaging types (laundry).

For liquid laundry detergent capsules, data were available to allow determining the relative market share of the two relevant packaging types, i.e. plastic tubs and stand-up pouches. This is further elaborated in Appendix 1. For these two packaging types, the percentage of accidental exposures - for those cases where the child had opened the original packaging (n=69) - was compared to the market presence (Figure 15). 91% [63/69] of such incidents had happened with a plastic box, and 9% [6/69] with a SUP. The market shares were respectively 83% and 17%. Hence, it can be concluded that, if anything (bearing in mind the accuracy of market data), Stand-Up Pouches have not been involved in more incidents per unit of capsules sold than plastic tubs.

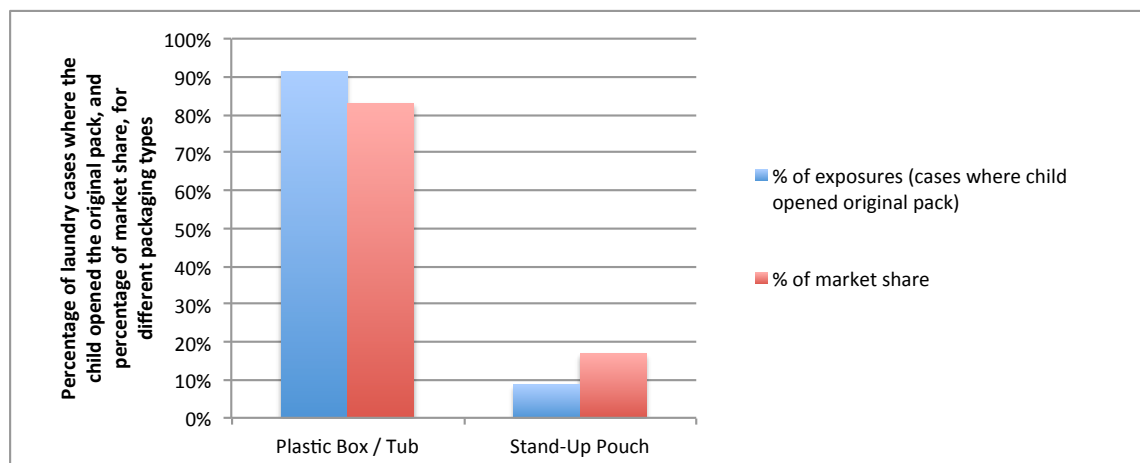


Figure 15. Incident frequency versus market share for different packaging types (laundry).

Transparent versus opaque packaging

The sales for transparent laundry packs have been essentially zero all through the project data collection period, as well as a substantial time (circa one year) before, since voluntary industry measures requiring opaque or obscure packaging have been implemented in 2013.

For laundry, incidents with transparent packs were reported sporadically by all of the participating PCCs (Dublin: 2 cases, Göttingen: 1 case, Milan: 4 cases, Utrecht: 6 cases, Prague: 1 case⁶).

For 71% [199/329] of the reported incidents, the packages were confirmed to be opaque or obscure (i.e. with reduced visibility of the capsules) (Figure 16). Only 4% [14/329] of the packs in the reported laundry cases were transparent. This shows that the voluntary industry commitments on laundry have been well implemented with near complete coverage (even though pre-PSP products appear to be still present in some consumers' homes).

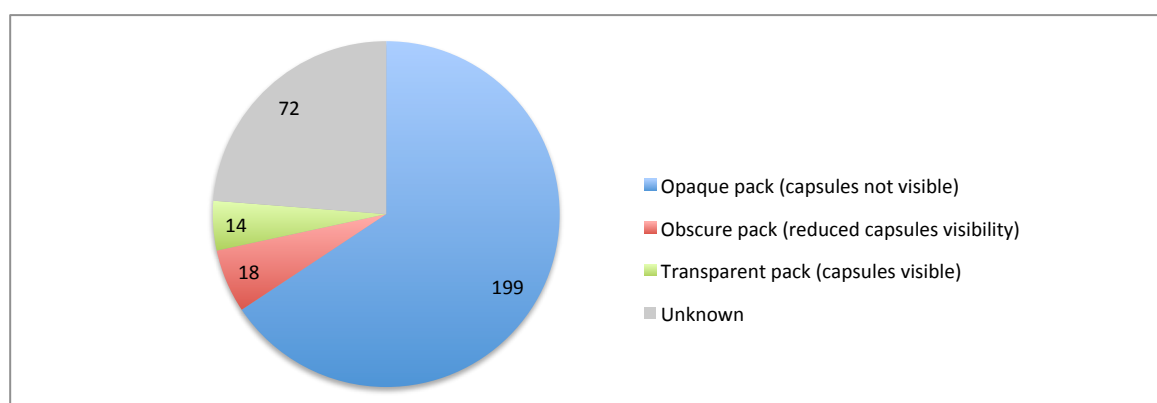


Figure 16. Visibility of the capsules through the packaging (laundry).

⁶ Note that as outlined higher, the Prague PCC had initially reported 11 additional cases with transparent packs, all occurring in the first month of the data collection (October) - these data were deemed to be invalid (due to a misinterpretation of the protocol) and were excluded from the assessment.

The impact of capsule visibility through the pack on incident frequency cannot be quantitatively assessed, because the remaining presence of such packs in households cannot be quantified.

Capsule colour

For 81% [266/329] of the laundry cases, unambiguous capsule colour information is available⁷. For 63 cases the colour was unknown (either reported as unknown: n=26, or set to unknown as outlined in the section 'limitations of the data set and data modifications': n=37). As shown in Figure 17, 41% [134/329] of the cases occurred with multi-coloured capsules. The most frequent single colours were blue and green (respectively, 17% [57/329] and 14% [47/329]) followed by purple (5% [17/329]). Other single colours were reported only sporadically (pink: n=4, red: n=3, orange: n=2, white: n=1, transparent: n=1).

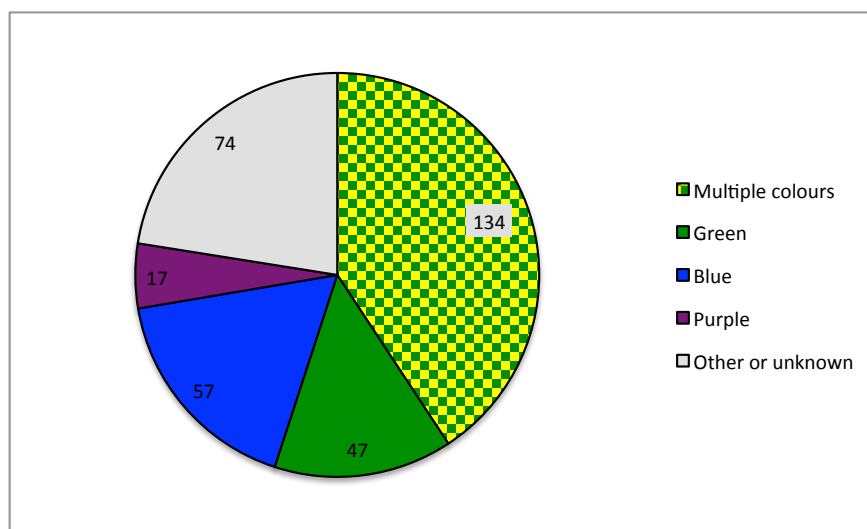


Figure 17. Incident count for different laundry capsule colours.

The percentage of incidents with each (known) colour was compared for all cases (n=262) versus the subset of cases where the capsule had been directly visible to the child (n=142). The latter are the cases where either the capsule had been outside of the container, or where the container had been left open. No apparent differences can be seen (Figure 18).

For liquid laundry detergent capsules, data were available to determine the relative market shares, in each country, of the different capsule colours (i.e. multi-colour, green, blue, purple, orange, yellow, transparent, pink, red and white). This is further elaborated in Appendix 1.

For each of the different colours and for each country, the number of accidental exposures was compared to the market presence (sales across the territory of the PCCs, during the 6-month data collection period)⁸. This country-by-country assessment of the number of reported cases per million capsules sold is shown in Figure 19⁹.

⁷ As outlined in Appendix 2, for 37 cases with laundry capsules (12% [37/329]), the reported colour designation did not match the colour of the reported (sub)brand. This may be either due to a misrepresentation of the colour, or due to the reporting of an incorrect brand name. Hence, for these cases, the colour was considered to be unknown (and consequently, excluded from further assessment). In 10 other cases, the brand identity and colour description were unambiguous, however, the description did not match the producer's designation as used for the determination of market shares for different colours. For these cases, the colour description in the data set was modified accordingly.

⁸ Note that for 4 cases, the reported brand (e.g. retailer label products or smaller brand) was not present in the market share review - and consequently, these 4 cases were excluded from this comparison.

⁹ To avoid disclosing information that may be associated with individual producers / brands, it is not possible to indicate which bars are linked to each of the different countries.

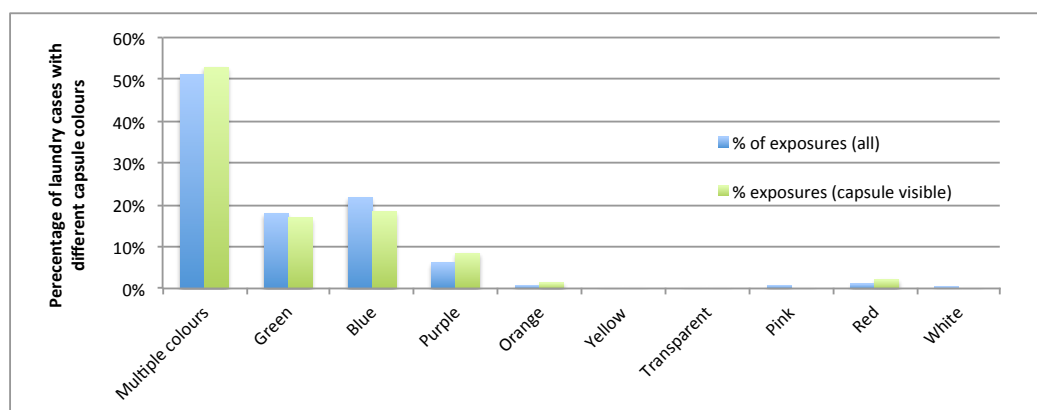


Figure 18. Incident frequency for different laundry capsule colours (excluding unknown).

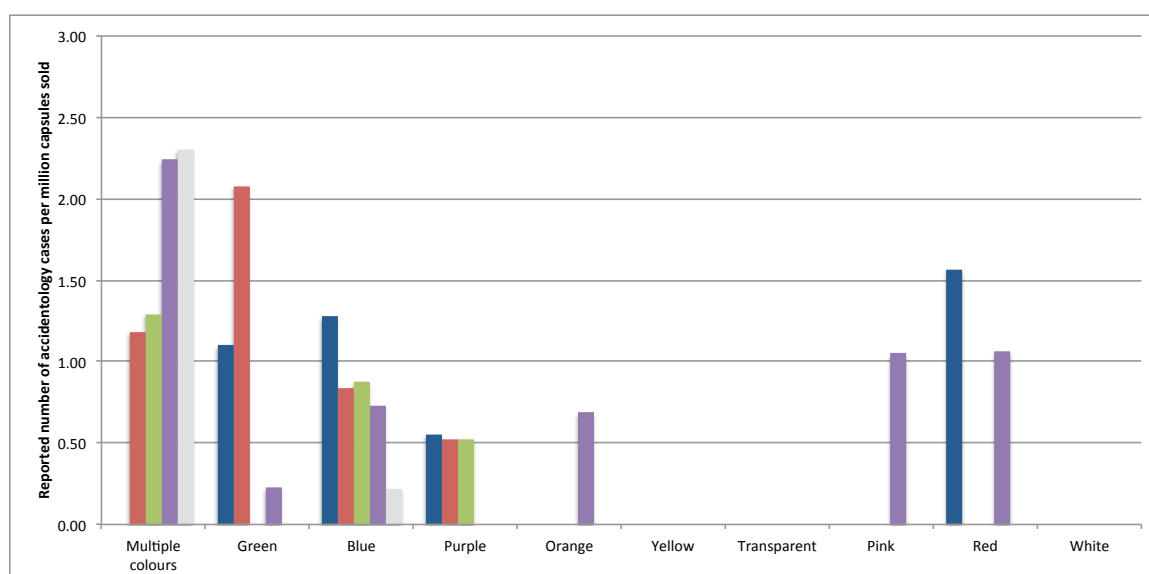


Figure 19. Number of reported exposures per million capsules sold, for each colour, split per country (different countries have different bar colours but are not named, to avoid indirect identifiability of individual brands).

Note that the calculated values for 'Green' are not relevant for two countries, because of a likely underestimation of the market size of green capsules in those countries - hence, these values are not shown in the chart. For several colours, this calculation shows substantial differences in the market-normalised incident frequency between countries. Furthermore, for different countries, other colours show up as the most frequently involved (relative to their market presence) in incidents.

There is no mechanistic or behavioural explanation for the observed differences between colours. And in different countries, opposite trends are observed. Consequently, the differences between colours are not likely to be meaningful, but rather to have been driven by other factors or by randomness. As there is essentially no market presence of non-coloured capsules (i.e. capsules containing colourless liquid detergent), this study did not allow assessing whether presence versus absence of colour (at product level) might have been a factor influencing accidental exposure.

To note: The potential impact on this assessment of the corrections made to the colour designations as originally reported by the PCCs (as outlined in Appendix 2), is very limited. This was verified by means of a sensitivity analysis, which is reported in Appendix 3.

Routes of exposure

92% [302/329] of all reported laundry cases involved ingestion (either as single route of exposure - 71% [234/329] of the cases; or combined with skin and/or eye exposure). Exposure to skin happened in 22%

[74/329] of the cases, and 11% [36/329] of the reported incidents included exposure to the eye. This is shown in Figure 20.

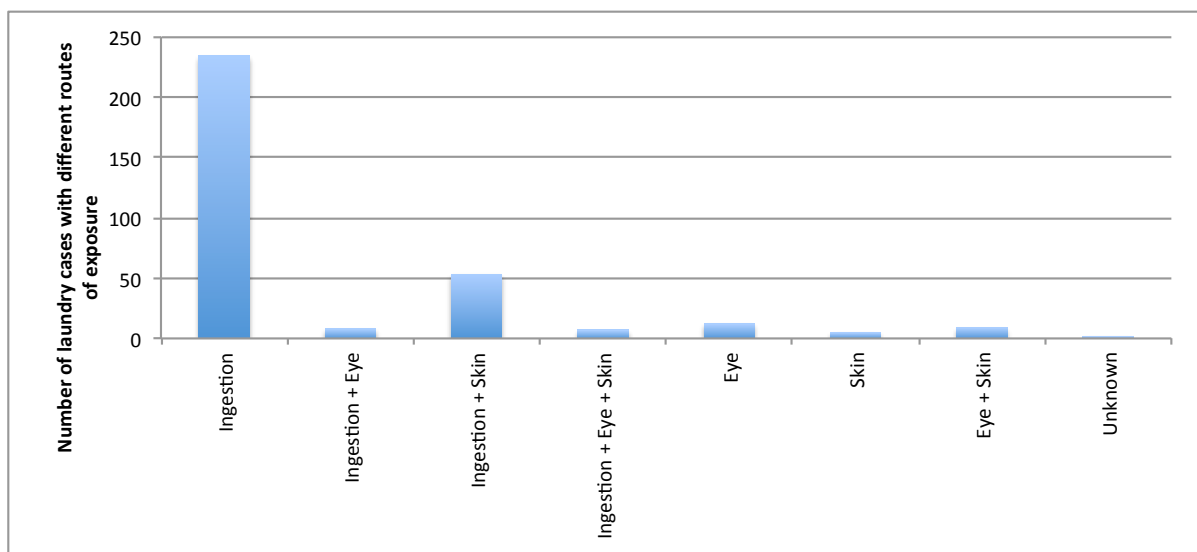


Figure 20. Different routes of exposure (number of cases - laundry).

For the assessment of how the capsules content was released, mentioning of 'biting' and 'licking' were combined into a single group 'biting, licking or sucking'. This is because, after the incident has taken place, it is not possible for the parent to differentiate. Indeed, as the parent has presumably not seen what happened, it is not possible to tell whether the child had or had not inserted the entire capsule into the mouth, or whether any bite strength had or had not been exerted on the capsule.

This oral contact was reported as a cause of the capsule's content release in 74% [251/329] of the incidents (Figure 21), consistent with the prominence of ingestion as exposure route. Squeezing (22% [73/329]) was also a relevant driver for content release. Leaks due to premature dissolution of the capsule from handling it with wet hands, or incidents with leaking capsules, were much less frequently reported (9% [28/329] of the cases).

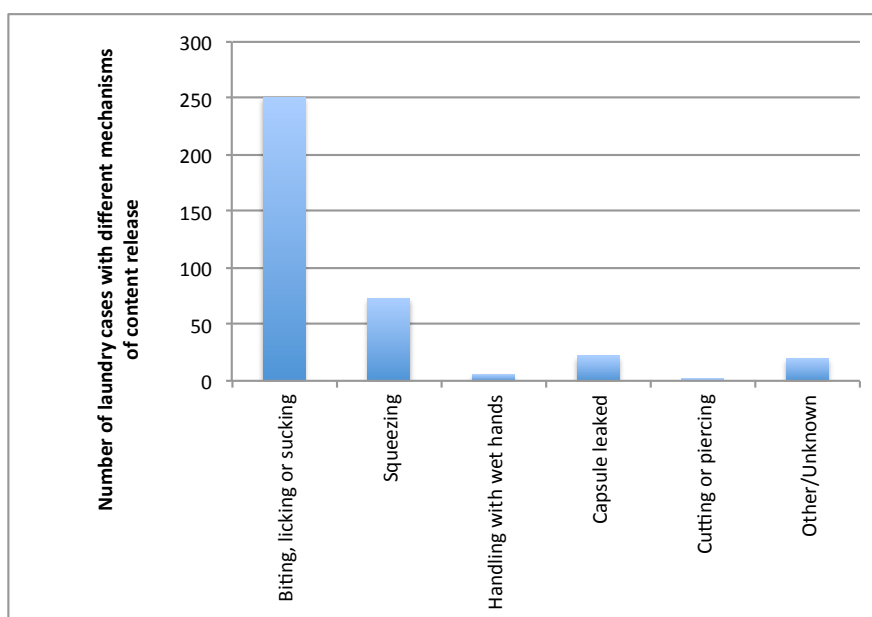


Figure 21. How the capsule's content was released (number of cases - laundry).

Symptoms

Causality

The causality of the symptoms following exposure to the laundry capsule was certain in most of the cases (92% [303/329]), and in nearly all (97% [32/33]) of the moderate cases (with PSS=2).

Symptoms description

For cases following ingestion, vomiting was by far the most prominent symptom. This was reported in 63% [190/302] of all laundry capsule ingestion incidents. Coughing occurred in 13% [40/302] of the ingestions, and also diarrhoea, inflammation and irritation of the oral mucosa were relevant symptoms (each reported for up to 10% of the ingestions [respectively 28/302, 26/302 and 14/302]). 5% [16/302] of the ingestion cases led to drowsiness. Dyspnea was reported in 4% [12/302] of the ingestions, and abdominal pain in 3% [8/302].

Cases with eye exposure were all symptomatic. Most of these exposures (86% [31/36]) led to irritation and/or inflammation of the eye, and to pain in the eye for 22% [8/36] of the cases. Photophobia, conjunctivitis, corneal abrasion, or temporarily impaired vision occurred in up to about 10% [each up to 4/36] of the eye exposures. It should be noted that only 36 cases of eye exposure (either only eye, or combined with other routes) were reported in total for laundry capsules, which is insufficient for a reliable quantitative assessment of the symptoms.

Skin exposures were much less symptomatic. They led to a rash, itching, and/or cutaneous hyperemia each in up to 8% [up to 6/75] of the cases. First-degree chemical burns (albeit with minor severity, PSS=1) were seen in 2 cases (i.e. 3% of the skin exposures).

The type of symptoms was largely in line with what was reported in Williams *et al.* (2014)¹⁰ for the UK, covering nearly 1500 exposure cases with liquid laundry detergent capsules.

Severity

67% [221/329] of the cases with laundry capsules led to minor symptoms (PSS=1), whereas 10% [33/329] caused moderate symptoms (PSS=2). 21% [69/329] remained without symptoms (PSS=0). This is shown in Figure 22. Compared to Williams *et al.* (2013), in the current study a higher percentage of cases was reported to be of moderate severity (10% of PSS=2, versus <3% of PSS>=2 in Williams *et al.*, 2014). On the other hand, Williams *et al.* (2014) reported 0.5% of cases with PSS=3 (severe), which were not encountered in the current study.

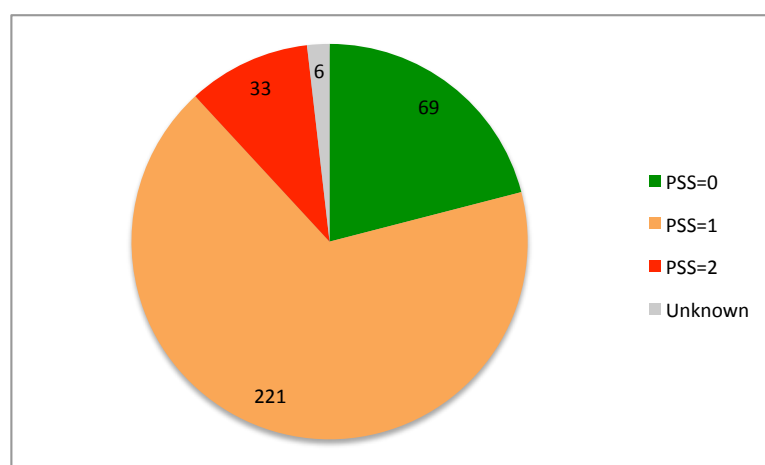


Figure 22. Symptoms severity (laundry).

¹⁰ Hayley Williams, Stephen Jones, Kelly Wood, Robert A. H. Scott, Michael Eddleston, Simon H. L. Thomas, John Paul Thompson & J. Allister Vale (2014) Reported toxicity in 1486 liquid detergent capsule exposures to the UK National Poisons Information Service 2009–2012, including their ophthalmic and CNS effects, *Clinical Toxicology*, 52:2, 136-140.

An assessment of severity by product form is irrelevant for laundry capsules, because essentially all reported cases were with entirely liquid product.

The severity scores were compared between the different routes of exposure (Figure 23). This suggests that for combined exposures, moderate symptoms (PSS=2) occurred comparatively more frequently than for exposures via a single route. Of all cases with a single route of exposure, 8% [19/251] had led to symptoms with PSS=2, whereas across all cases with multiple exposure routes, this was 18% [14/77]. 8% [18/229] of the single-route ingestion cases led to symptoms with PSS=2. This percentage was the same for eye exposures, 8% [1/12] (inconclusive as there was only one such case).

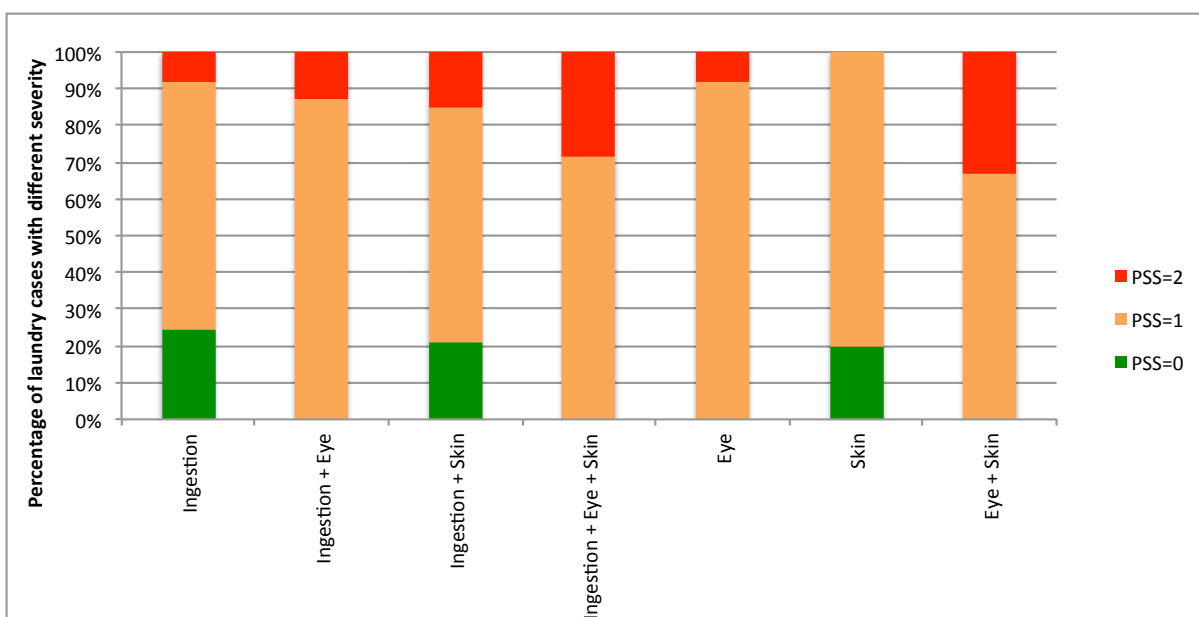


Figure 23. Severity (where known) for different routes of exposure (laundry).

Automatic dishwashing (ADW) capsules

Product form

77% [49/64] of the ADW cases were with partly liquid, partly solid product (Figure 24). Further, there were 9 cases (14% [9/64]) with entirely solid product, and 5 cases (8% [5/64]) with entirely liquid product. For 1 case the product form was reported to be unknown.

As highlighted in the section about the limitations of the data set and data modifications, 29 ADW cases had to be excluded from the assessment because they were most likely not with soluble film containment. Furthermore, for 5 cases with entirely solid product, the product form was corrected as they had been reported as “part liquid, part solid”.

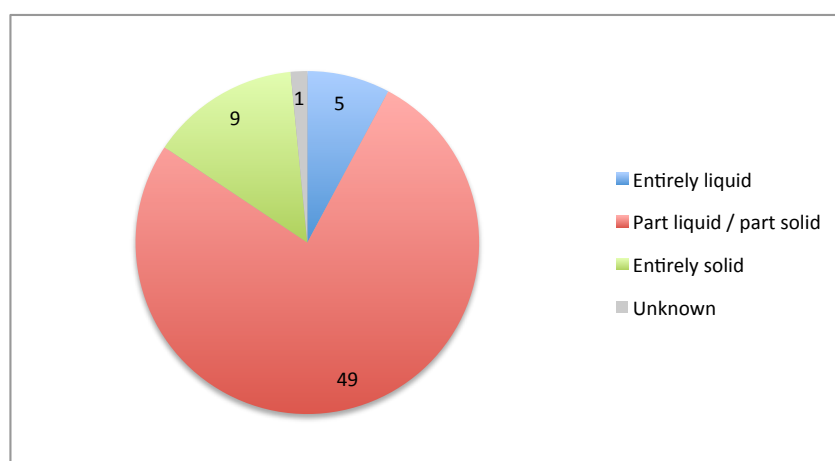


Figure 24. ADW product forms.

Access to the products

An overview is shown in Figure 25. For 72% [46/64] of the ADW cases, information was available whether the capsule had been in a container when the accident happened. The further assessment focuses on these cases with known information.

Cases where the child had direct access to the capsule

In 43% [20/46] of the incidents with ADW products, the capsule was not in a container when the incident happened¹¹. For 45% [9/20] of these cases, more detailed information is available about the exact circumstances, which is a too low sample size to allow a quantitative assessment. The following circumstances were reported (each equally frequently): misplaced or lost capsules; capsules taken by the child during the preparation of the dishwashing process; and capsules given to the child.

Cases where the child took the capsule from a container

In 57% [26/46] of the ADW cases, it was reported that the capsule had been in a container before the incident happened - i.e. that the capsule had not yet been taken out of the pack. This sample size is too low for any conclusive assessment, but the observations are as follows. Most frequently, in 42% [11/26] of these cases, the capsules had been in the original pack, but this had not been (properly) closed. In 27% [7/26] of such cases, the capsules had been stored in their original packaging and this had been properly closed. 5 cases (19% [5/26]) occurred with product that had been stored in a non-original container.

¹¹ The impact on these findings of the corrections made to the originally reported data is assessed in App. 3.

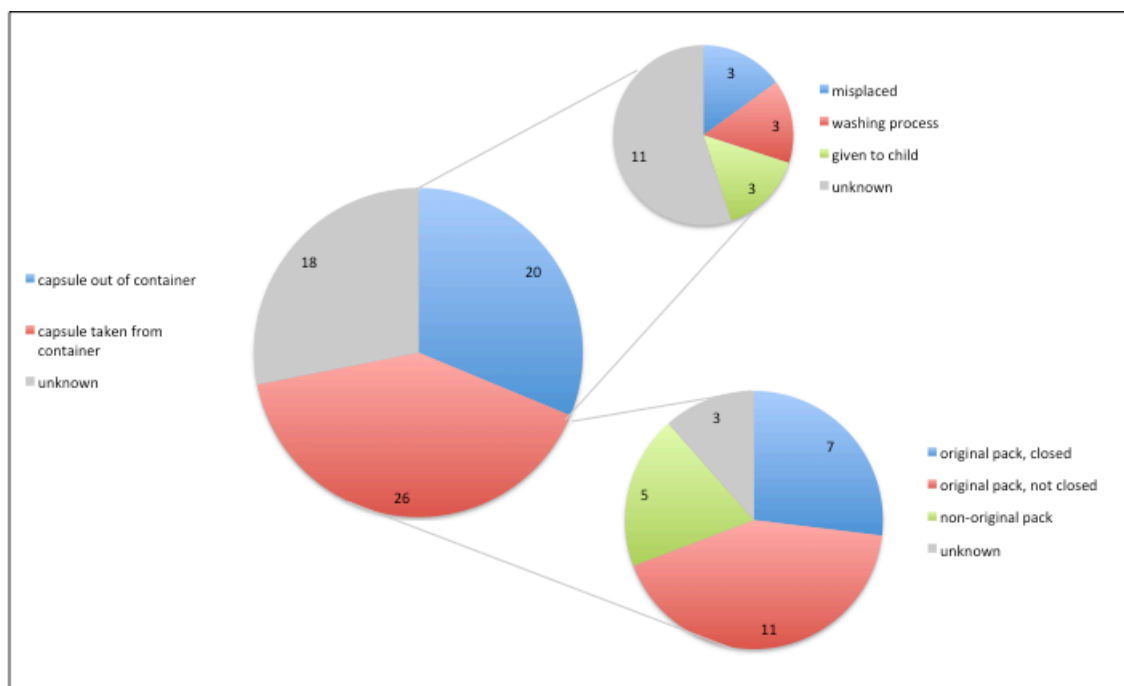


Figure 25. Access to ADW capsules - overview (note the limited sample size).

Child-safe storage

Only in 27% [7/26] of the cases where the product had not been already taken out of the pack, the products had been stored in a safe way (i.e. in a high shelf or cabinet, and/or in a cabinet secured by a child-safe lock).

In 38% [10/26] of these situations, on the other hand, the packs had not been stored safely. Either they were in a cabinet under the sink without child-safe lock (31% [8/26]), or in 2 cases on the kitchen counter (8% [2/26]). For 35% [9/26] the exact storage location was not known but it was reported that no child safety had been put in place. This is illustrated in Figure 26.

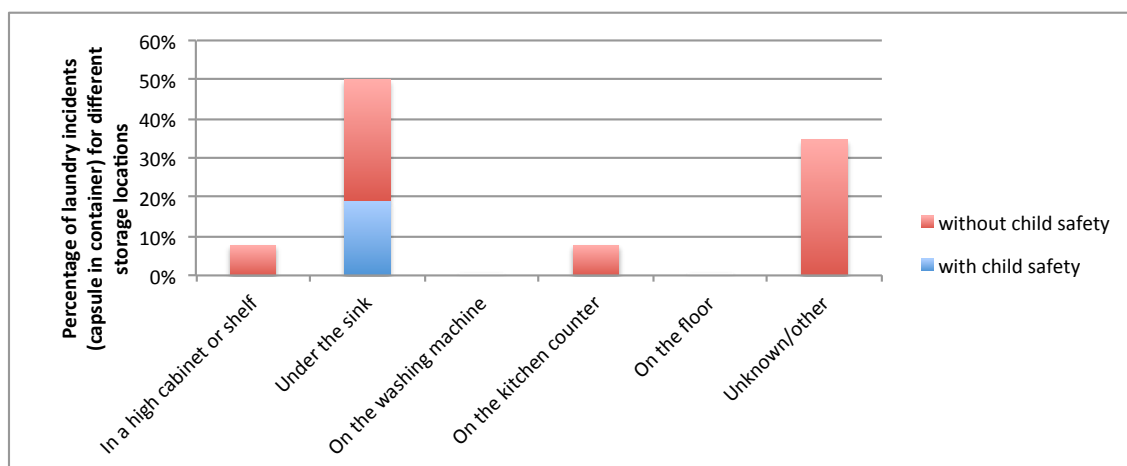


Figure 26. Storage location of ADW detergent capsule packs, for incidents where the capsule had been in a container.

Packaging Type

Incident frequency for different packaging types

Over half of the incidents with ADW capsules (56% [36/64]) happened with product in SUPs. The remainder of the cases were with plastic boxes (23% [15/64]) and cartons (19% [12/64]) (Figure 27).

No detailed market share data are available for different ADW packaging types. Hence, a market share normalisation could not be conducted.

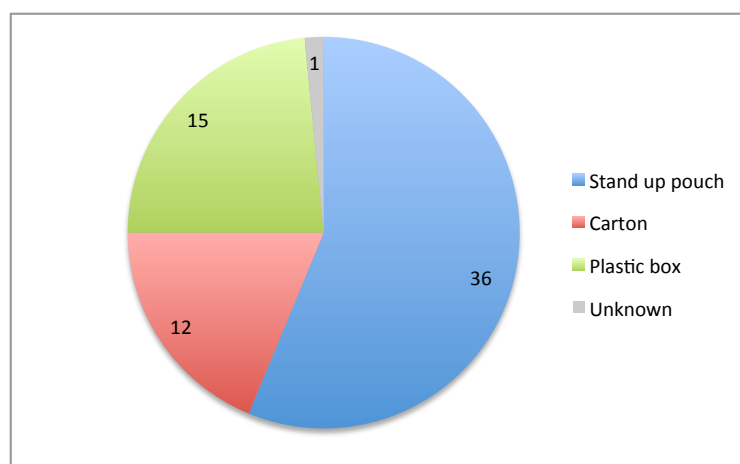


Figure 27. Incident count for different packaging types (ADW).

Capsule colour

Most ADW cases occurred with multi-coloured capsules (91% [58/64]). In addition there were 2 cases with green and 4 cases with blue capsules (Figure 28).

No detailed market share data are available for different ADW capsule colours. Hence, a market share normalisation could not be conducted.

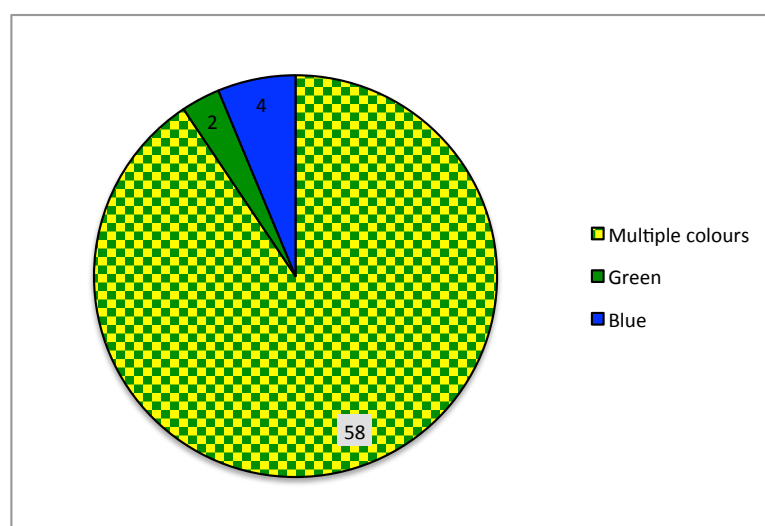


Figure 28. Incident count for different ADW capsule colours.

Routes of exposure

Ingestion was by far the most important route of exposure for ADW capsules (Figure 29). All but one of the reported cases (98% [63/64]) involved ingestion (of which mostly as single route of exposure - 92% [59/64] of the cases). Eye exposure happened in two isolated cases (one of which in a combined exposure with ingestion and skin). Single-route skin exposures were not reported, but there were 4 cases of combined exposure also involving skin.

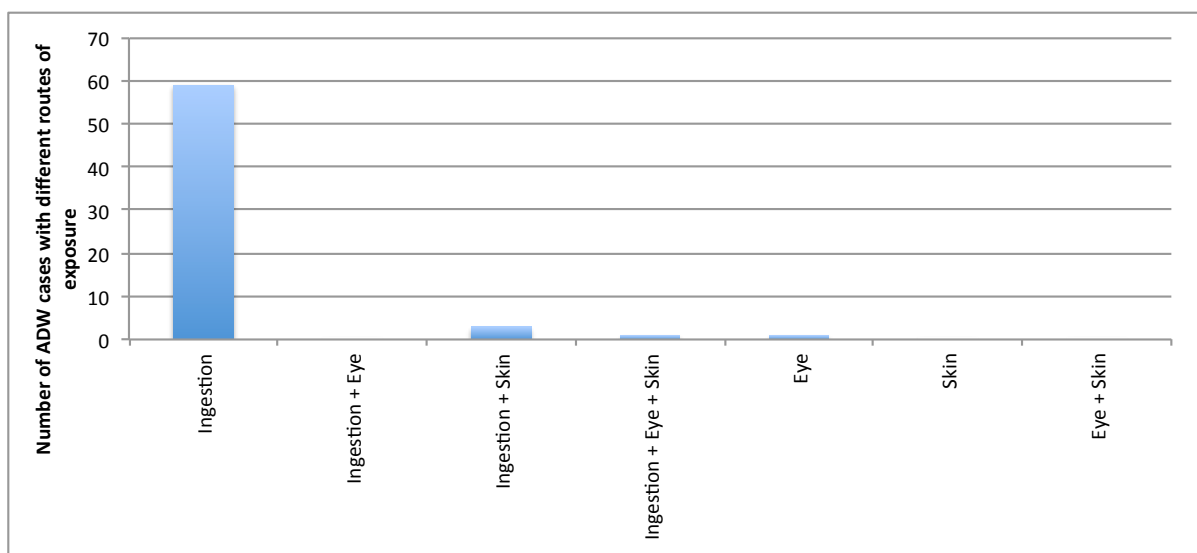


Figure 29. Different routes of exposure (number of cases - ADW).

For the assessment of how the capsule content was released, mentioning of 'biting' and 'licking' were combined into a single group 'biting, licking or sucking'. This is because, after the incident has taken place, it is not possible for the parent (who has not seen up close what had happened) to differentiate - i.e. whether the child had or had not inserted the entire capsule into the mouth, or whether any bite strength had or had not been exerted on the capsule. This was by far the main cause of the capsule content release - reported for 85% [57/64] of the ADW cases (Figure 30), in line with the predominance of ingestion as exposure route. In 5% [3/64] of the cases it was reported that the capsule had leaked.

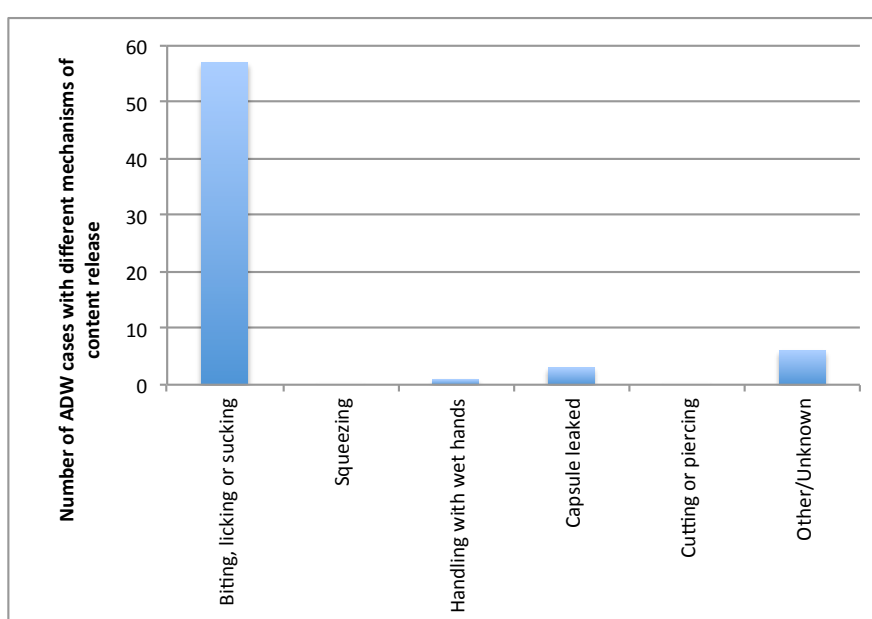


Figure 30. How the capsule's content was released (number of cases - ADW).

Symptoms

Causality

The causality of the symptoms following exposure to an ADW capsule was certain in a majority of the cases (77% [49/64]).

Symptoms description

For cases following ingestion (i.e. all but one of the reported ADW exposures), vomiting happened with 25% [16/63] of the exposures. Coughing occurred in 8% [5/63] of the ingestions. Diarrhoea, inflammation/irritation of the oral mucosa and drooling were reported for isolated cases.

Cases with eye exposure were rare (only two exposures). These led to irritation and inflammation of the eye, and one case led to palpebral edema. Clearly the number of cases is too low for a meaningful assessment.

Skin exposures only happened in combination with ingestion and/or eye exposure (4 exposures in total). No skin related symptoms were reported for these cases.

Severity

58% [37/64] of the ADW exposures remained without symptoms (PSS=0) (Figure 31). The other cases (36% [23/64]) led to minor symptoms (PSS=1) except for a single isolated case with PSS=2. The symptoms of the latter were mainly vomiting and diarrhoea, as well as coughing and breathing difficulties. However, the child had been ill with a cold prior to the exposure, and already suffered from fever and coughing - which may have worsened the situation.

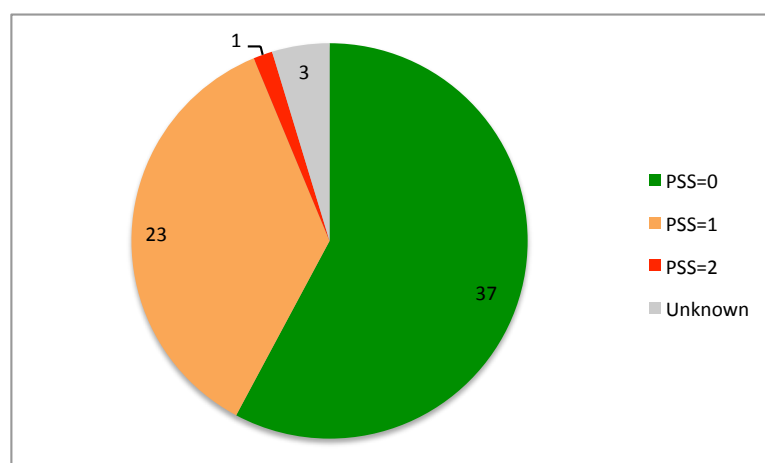


Figure 31. Symptoms severity (ADW).

Different ADW capsule product forms are present on the market. However, due to the very limited number of cases with entirely liquid and entirely solid product, it could not be assessed whether there may be any difference in severity between these different forms.

The severity scores were compared between the different routes of exposure. Given the predominance of the ingestion route, the severity of these cases is equivalent to the overall findings for ADW: 59% [37/63] asymptomatic, 35% [22/63] minor symptoms (and the one isolated case with PSS=2). Both cases involving eye exposure led to symptoms, albeit always minor (PSS=1). No skin-related symptoms were reported.

Comments made by the parents

In 132 cases (33% [132/401]), the parents provided suggestions how the product might be made safer. Most suggestions (85% [112/132]) were made for Laundry, whereas 18 suggestions (14% [18/132]) were received for ADW. This is proportional to the overall number of reported incidents with both product categories.

As these data were collected a few days after the parents had gone through a traumatic experience, it should be noted that these comments may be subject to some bias.

Laundry capsules

Attractiveness

In 18 cases, parents reported that the product looked like candy, and in 5 out of these cases they mentioned that the child had actually mistaken the capsule for candy. In 10 cases the parents mentioned that the product was attractive to children, in 6 cases that it looked like a toy. One parent said that the child liked to squeeze the capsule and watch the bubbles. In 2 cases a resemblance to 'Smurfensnot' (a kind of toy-soap) was mentioned.

In 33 cases the parents recommended to change the colours (e.g. remove the colours, change the colours, make the capsule opaque, make the capsule look nasty). In 15 cases the recommendation was given more generally to reduce attractiveness.

Packaging

In 12 cases the parents reported that the packaging was easy to open by children. Interestingly, in one case (a plastic tub) it was said that the pack was too difficult to reclose for the parents.

Overall, in 41 cases the parents recommended that the child resistance of the packaging should be improved. Hence, this is the most frequently reported recommendation by the parents.

Product

In 12 cases the parents recommended to make the soluble film stronger. 3 times it was advised to enclose the capsules in a separate disposable wrapper. In 1 case the parents recommended to include an aversive agent in the product, and in another case it was suggested to make the composition less hazardous. 6 parents indicated that they would no longer buy this product (in one case a ban was suggested).

Automatic dishwashing capsules

Note that the number of spontaneous inputs from the parents is very limited (resulting from the low number of reported incidents within ADW capsules).

Attractiveness

In 2 cases, the parents reported that the product looked like candy, and in 1 of these the child had indeed mistaken the capsule for candy. Child attractiveness in general was reported in 2 cases. In 5 cases the parents recommended to change the colours, and in 2 cases to reduce attractiveness.

Packaging

In 2 cases the parents reported that the packaging was easy to open by children. 7 times the parents recommended that the child resistance of the packaging should be improved.

Product

In 3 cases the parents recommended to make the soluble film stronger. Once it was questioned why the composition is so hazardous.

Conclusions

Background

To better understand the causal factors for accidental exposures to detergent capsules, A.I.S.E. partnered with five Poison Control Centres across Europe (Dublin, Göttingen, Milan, Prague, Utrecht) to conduct a prospective 'accidentology' research study. The scope covered all detergent capsules (laundry, dishwasher, and others) contained in a water-soluble film. Over a 6-month period, starting in autumn 2014, data on 401 cases were collected.

General

82% of all reported incidents were with liquid laundry detergent capsules. Automatic dishwashing capsules represented 16% of the cases.

74% of the incidents happened with children of less than 3 years old, and the age group of 12-24 months was most prominently at risk (representing nearly half of all exposures). As of the primary school age, the number of incidents had become very limited. Incidents without oral exposure generally happened with somewhat older children (for these cases, the 24-36 months old group was most frequently involved). There was no indication that the children were typically older for exposures where they had opened the packs themselves. There was no difference between males and females. Families with only one child appeared to be somewhat more frequently involved in incidents - which is in line with PCC enquiries overall.

Nearly all incidents happened at home, mostly in the room where the detergent products are normally used or stored. No specific days of the week were identified where incidents were more frequent. Incidents occurred quite uniformly all through the day, with to some extent increases around lunchtime and before supper, which is in line with PCC enquiries overall.

Across all exposures for which this information is available, in 33% of the incidents the capsule had not been in a container, and in another 33%, the capsule had been in a container that was not stored in a child-safe location. In 26% of all exposures with the relevant information available, the child had opened the original packaging to gain access to the capsule. This is 44% of those accidents (where known) where the child had taken a capsule from a container.

Laundry

32% of the incidents (where this is known) happened with capsules that had already been taken out of their pack. This happened mostly when the child had been able to take a capsule that was ready for use in the laundry process, or when a capsule had been misplaced or lost. In addition, seven cases were reported where the parents had intentionally given the capsule to the child.

In 68% of the incidents (where this is known), the child had taken a capsule from the container in which it was stored. In 55% of these cases (where known) the pack closure had not been a barrier, either because the original pack had been left open (48%) or because a non-original pack had been used (7%). However, in 45% of these cases (where known), the child had opened the (properly closed) original packaging to get access to the capsule. Only 25% of the incidents where the child had taken a capsule from its pack happened despite the fact that this pack had been safely stored, out of children's reach (either in a high place, or in a cabinet with a child-safe lock). Between the two different packaging types on the market (i.e. boxes and stand-up pouches), if anything, SUPs have not been involved in more incidents per unit of capsules sold than plastic tubs.

The number of incidents involving laundry capsules with different colours was compared to the market presence of each colour, per country. The observed differences were inconsistent and contradictory between countries. It can be concluded that different colours did not lead to a different risk for incidents. However, because there is essentially no market presence of non-coloured capsules, the study did not allow assessing whether presence versus absence of colour might have been a causal factor.

Ingestion was by far the most prominent route of exposure (92%). Most often (67%) the capsule content was released due to biting, sucking, or licking. Squeezing was a less important but still relevant driver. On the other hand, premature dissolution of the capsule (e.g. from handling it with wet hands) was reported much less frequently.

77% of the cases with laundry capsules had symptoms: 67% of the cases led to minor symptoms, and 10% caused moderate symptoms. The latter were more frequently reported for cases with multiple routes of exposure. No severe symptoms (PSS>2) were seen. 2% of the patients (n=7) had been hospitalised. For ingestion, vomiting was very prominent (62% of all ingestions), distantly followed by coughing, diarrhoea and mucosal inflammation. All eye exposures were symptomatic, usually leading to eye irritation or inflammation. Skin exposure led to skin irritation less than 10% of the time.

Automatic dishwashing

77% of the incidents with ADW capsules were with partly liquid, partly solid product - in addition to some exposures with entirely liquid or with entirely solid products.

43% of the ADW incidents (where this is known) happened with capsules that had already been taken out of their pack. In 57% of the incidents (where known), on the other hand, the child had taken a capsule from the container where it was stored. It is worth noting that most of these cases happened when the pack closure had not been a barrier - i.e. the capsule was taken from an open original pack (42%) or from a non-original pack (19%). In 27% of these cases, the child had gained access to the capsule by opening the properly closed original packaging. Only in 27% of the incidents where the child had taken a capsule from its pack, this pack had been safely stored, out of children's reach (either in a high place, or in a cabinet with a child-safe lock).

With only isolated exceptions, ingestion was the route of exposure, and biting, sucking or licking the mechanism of the capsule content release.

58% of the ADW cases were asymptomatic. Hence, ADW exposures were not only five times less frequent, but in addition, also twice less symptomatic than exposures to laundry capsules, highlighting the more favourable safety profile of the ADW capsule category. The remainder of the ADW cases (36%) led to minor symptoms, with only one exception (1.6%) that had PSS=2. Vomiting happened in 25% of the cases, followed by coughing (8% of the exposures). These conclusions confirm what was reported¹² in June 2014 by the Milan PCC Niguarda i.e. that the safety profile of ADW soluble film capsules is equivalent to (or even better than) the one of the traditional ADW detergents forms (powders, liquids and tablets).

¹² Cases of exposure to dishwashing detergents examined by the Poisoning Control Center of Milan, Years 2004-2013, Date of Report: June 6th 2014

Recommendations by the Poison Control Centres

Based on their professional judgement and on the interpretation of the data collected in the study, the Poison Control Centres recommend the following:

1. There is an opportunity to improve the child-impeding properties of the closures for the products of concern. In 26% of all accidental exposures in the accidentology study (where this information was known), the child had managed to open the original pack. This is 44% of the accidents where the child had taken a capsule from a container. It is recognised that closures must continue to be convenient and easy to use (open and re-close, across the lifetime of the packaging) for adults, to avoid that they be left open. It was acknowledged that 'true Child Resistant Closures' as currently implemented e.g. on corrosive products may be disproportionate. Nevertheless the closures as present on the market at the time of the accidentology data collection are judged by the PCCs as insufficiently child-impeding.
2. Consumer education continues to be an essential aspect in risk reduction. The accidentology study shows that a majority of cases might have been avoided by keeping the capsules safely away and out of reach of children. The safe use message should target all families, but should be especially aimed to reach first-time parents whose children appear to be slightly more at risk. To ensure the education penetrates well it should be sustained over time, e.g. as currently achieved with TV advertising tag-ons to all commercials for laundry capsules. The safe-use communication should focus on three aspects:
 - Always keep detergent capsules safely out of the reach of children;
 - Always store these products in their original container;
 - Never give a detergent capsule to a child.
3. The PCCs judge that there is an opportunity to make the capsules less attractive to children. The PCCs believe that liquid detergent capsules are attractive due to a combination of aspects. Even though in this study it was shown that different colours do not lead to a different incident risk, the PCCs judge that presence of colour may be a driving factor. Also the capsules' sensorial aspects ("touch and feel") are judged by the PCCs as a potential factor. As the accidentology study did not allow to quantitatively and objectively assess child-attractiveness, further research is recommended. It should be identified which aspects of the product category are the most important drivers for child-attractiveness and which modifications may be proposed to reduce attractiveness.

Appendix 1 - Laundry: Market Shares for Different Product Attributes

For liquid laundry detergent capsules, it was possible to determine the relative market share of the two relevant packaging types (i.e. plastic tubs and stand-up pouches) and of the different capsule colours (Table 2). For automatic dishwashing capsules, underlying sales data were not available at a sufficient level of detail to determine these relative shares.

The share information was calculated by The Nielsen Company, by combining the Nielsen sales data on an individual country and individual SKU basis (stock keeping unit = a specific brand, sub-brand and size), with information about the packaging type and capsule colour for each SKU. The latter information was provided by the A.I.S.E. member companies. The time horizon used for this calculation was the one-year period from week 29 of 2014 until week 28 of 2015. This covers the accidentology data collection period itself, as well as several months before, when consumers may already have purchased the product that afterwards led to an incident.

It should be noted that for Germany, packaging data for individual SKUs was not readily accessible, and hence, a different approach was followed. The estimate of the relative shares of the two packaging types was kindly provided by Henkel.

Table 2. Market shares for different laundry product attributes - mid 2014 until mid 2015 - provided by The Nielsen Company.

	Ireland	Germany	Italy	Czech Republic	The Netherlands
<i>Packaging types</i>					
Plastic Box/Tub	89%	40% (*)	82%	86%	86%
Stand-Up Pouch	11%	60% (*)	18%	14%	14%
<i>Capsule colours</i>					
Multi-colour	7%	43%	48%	45%	42%
Green	19%	0%	3%	5%	35%
Blue	45%	56%	33%	24%	11%
Purple	19%		14%	26%	0%
Orange	3%				6%
Yellow	0%				
Transparent	0%				
Pink	5%			0%	2%
Red	2%		3%		2%
White					2%

(*) estimate provided by Henkel

Next, the relative shares of the different packaging types and of the different colours were combined with estimates of the total laundry capsule sales in the territory covered by the different PCCs (Table 3). Sales data are expressed in number of capsules during the accidentology data collection period (i.e. 6 months from October 2014 through March 2015). Per country, the liquid laundry detergent capsule sales estimates (for the entire market, all producers) were obtained from different detergent companies, and an average of the different data sources was used. This is the same approach as followed for the A.I.S.E. status reports on the Product Stewardship Programme. No further details can be reported here, as the underlying data are confidential business information owned by the individual companies. For Germany, in absence of more detailed data, the market size was estimated to be 100 million capsules per year (based on Euromonitor data). PCC coverage was 100% for IE, NL and CZ. For DE the coverage percentage was estimated from the population of the Länder Bremen, Hamburg, Niedersachsen und Schleswig-Holstein versus the total population of Germany. For IT the coverage was based on information from the PCC.

Table 3. Liquid laundry detergent capsule sales data (million capsules sold during the 4th quarter of 2014 + 1st quarter of 2015).

	Ireland	Germany	Italy	Czech Republic	The Netherlands
Entire country (mio caps sold)	28.2	50	139.6	43.3	49.2
PCC coverage %	100%	16%	70%	100%	100%
PCC territory (mio caps sold)	28.2	8	97.7	43.3	49.2

Combining the estimated total laundry capsule sales per PCC territory with the relative shares for each product attribute, leads to the number of capsules sold during the accidentology data collection period, covered by each considered PCC, for each of the packaging types and of the capsule colours (Table 4):

Table 4. Sales estimate per PCC territory, for the different product attributes mid 2014 until mid 2015, million laundry capsules.

	Dublin	Göttingen (*)	Milan (*)	Prague	Utrecht
<i>Packaging types</i>					
Plastic Box/Tub	24.9	3.2	80.0	37.3	42.5
Stand-Up Pouch	3.2	4.8	17.7	6.0	6.7
<i>Capsule colours</i>					
Multi-colour	1.9	3.5	46.5	19.4	20.5
Green	5.4	0.0	2.9	2.2	17.4
Blue	12.6	4.5	32.2	10.3	5.5
Purple	5.4	0.0	13.3	11.4	0.0
Orange	0.9	0.0	0.0	0.0	2.9
Yellow	0.0	0.0	0.0	0.0	0.0
Transparent	0.0	0.0	0.0	0.0	0.0
Pink	1.4	0.0	0.0	0.1	1.0
Red	0.6	0.0	2.8	0.0	0.9
White	0.0	0.0	0.0	0.0	1.0

(*) for DE and IT it is assumed that the relative market shares for the country are also applicable to the territory covered by the PCC.

The sum of the sales across the 5 participating PCCs, as well as the relative market share across this territory for the different product attributes, is presented in Table 5 and Table 6.

Table 5. Total sales estimates and shares for different laundry packaging types across all participating PCCs - mid 2014 through mid 2015

	Million capsules	Relative Share
<i>Packaging types</i>		
Plastic Box/Tub	187.9	83%
Stand-Up Pouch	38.5	17%

Table 6. Total sales estimates and shares for different colours of laundry products across all participating PCCs - mid 2014 through mid 2015

	Million capsules	Relative Share
<i>Capsule colours</i>		
Multi-colour	91.7	41%
Green	27.9	12%
Blue	65.0	29%
Purple	30.1	13%
Orange	3.8	2%
Yellow	0.03	0%
Transparent	0.0001	0%
Pink	2.4	1%
Red	4.4	2%
White	1.0	0%

Appendix 2 - Laundry: Capsule Colour Modifications

Across the data set, the colour indication for laundry capsules was modified in 47 cases (Table 7).

- For 10 cases with a specific brand, the colour had been reported as 'Multiple Colours'. Whereas these are multi-compartment capsules, they are identified as having a single colour blue (albeit in two shades).
- For 37 cases, the reported colour was not consistent with the supplier information about the colour for the reported brand - or the reported colour was not present in that market. These cases were excluded from further (colour) assessment by indicating the colours as "Unknown".

Table 7. Corrections made to colour indication.

	Brand	Reported Colours	Corrected Colour	Rationale
Göttingen (6 corrections)	Persil Duo-Caps (sub-brand not known) (6x)	Multiple colours	Unknown	Persil Duo-Caps can be multi-coloured (blue/green) or single-colour (two shades of blue), depending on the sub-brand.
Milan (6 corrections)	Dash Ecodosi con Ammorbidente (different variants) (4x)	Pink	Unknown	These products are indicated by the producer as 'Purple' or 'Blue' depending on the variant, but never as 'Pink'.
	Dixan Classico Duo-Caps (2x)	Multiple colours	Blue	Dixan duo-caps with additional colour information 'blue and light blue' are considered as single colour blue capsules.
Prague (15 corrections)	Persil Duo-Caps (4x)	Multiple colours	Blue	Persil duo-caps with additional colour information 'blue and light blue' are considered as single colour blue capsules.
	Several (11x)	Transparent	Unknown	None of these products have transparent contents - by mistake, transparent refers to the film instead of the detergent (as confirmed by the PCC).
Utrecht (20 corrections)	Ariel '3 in 1' or 'pods' (8x)	Purple, Green, Blue	Unknown	The colour description (single colour) is inconsistent with the brand name, hence, either the colour or the brand name may be incorrect.
	Ariel color (not 3-in-1) (12x)	Purple	Unknown	Single-colour purple Ariel capsules have never been on the NL market.

Appendix 3 - Sensitivity analysis for corrected aspects

Colour

As outlined in Appendix 2, laundry capsule exposures for which the colour designation was not in line with the reported brand name, or where this was ambiguous, were excluded from the colour assessment.

To assess the impact of this approach, two alternative methods were also applied, as a sensitivity analysis:

- use of the data as originally reported by the PCC.
- 'best guess' of what should most likely have been the colour designation, based on the brand name and on additional free text information in available.

The outcome of this sensitivity analysis (i.e. the percentage of laundry exposures per colour, for the different scenarios) is presented in Figure 32. Only minor differences are seen - which do not impact the conclusions.

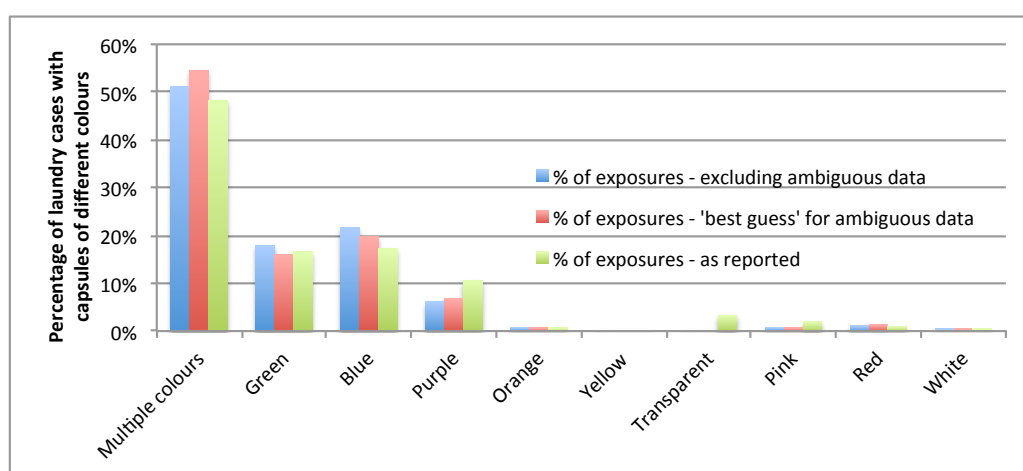


Figure 32. Sensitivity analysis: laundry capsule colour designation.

Access: capsule already out of pack

For 21 cases, a correction was made to reflect that the capsule had already been outside of the container when the accident took place. In Table 8 the comparison is shown between the assessment for the original versus the amended data. After the correction, the percentage of cases where the capsule was not in a container when the child got access to it, is overall 26% higher. Whereas this increases the relevance of such cases, it does not impact the overall conclusion that situations where the capsule was not in a container is a relevant exposure scenario.

Table 8. Sensitivity analysis: correction whether capsule was already out of the container.

% of exposures to capsules that had not been in a container	Laundry	ADW
As originally reported	19.8%	23.4%
	[65/329]	[15/64]
After correction	24.6%	31.3%
	[81/329]	[20/64]

Appendix 4 - Cases for which no follow-up was possible

Accidentology follow-up success rate

Accidentology data collection requires follow-up beyond the initial contact between the patient/parents or their medical doctor and the PCC. For several reasons, this is not always feasible.

For laundry capsules, the total number of exposures reported to each of the PCCs during the data collection period is known. This allows determining the percentage of cases where accidentology follow-up was possible - which was 70% across all participating PCCs (Table 9).

Table 9. Accidentology follow-up rate for cases with laundry capsules.

PCC	Total reported exposures	Accidentology cases	Follow-up success rate
Dublin	69	27	39%
Göttingen	18	17	94%
Milan	113	113	100%
Prague	142	88	61%
Utrecht	124	84	68%
OVERALL	466	329	70%

The lower than average follow-up rate in the Dublin PCC is explained by the fact that many calls were from General Practitioner co-ops, who provide cover for family doctors during weekends and between 6pm and 8am on weekdays. Many of these GP co-ops refused to recruit their clients into the study. If only the eligible cases are considered the follow-up rate was 78%.

The follow-up rate achieved by the Utrecht PCC - which can only be contacted by medical professionals - was similar to the overall average rate. This was possible thanks to dedicating one temporary staff member specifically to this project. But it also gives an indication of the willingness of medical doctors in the Netherlands to collaborate with this kind of research.

The Milan PCC achieved a 100% follow-up rate, thanks to the perseverance of the staff member responsible for this task, and thanks to the experience that this PCC had already built up on similar data collection over the previous years.

Cases for which no follow-up was possible

The Utrecht PCC and the Dublin PCC received respectively 47 and 45 enquiries for which no further accidentology follow-up was possible. Similar to the cases included in the accidentology study, 89% [82/92] were with laundry capsules, while 9% of these cases [8/92] (only reported in Utrecht) were with ADW. 89% [82/92] of the incidents without further follow-up had ingestion as (one of the) route(s) of exposure, whereas 13% [12/92] included exposure to the eyes. This is in line with what is seen for the overall accidentology data set. Vomiting was the most prominent symptom, reported in 47% [43/92] of the cases (somewhat less than the overall data set). 64% of the cases [59/92] was symptomatic, mostly (60% [55/92]) with minor symptoms. Moderate symptoms (PSS=2) were observed in 4% of the cases [4/92].

For the Prague PCC, whereas no further details are available, it was reported that none of the cases that were lost to follow-up were with PSS \geq 2.

Overall it can be concluded that exclusion of these cases where follow-up was not possible, is not expected to have impacted the findings of the accidentology study. If anything, the cases without follow-up were somewhat less symptomatic, and had a lower percentage of cases with moderate severity.

Appendix 5 - Accidentology Study Protocol (15/9/2014)

Background

Detergent capsules (primarily for laundry and automatic dishwashing; more recently also for cleaning products) are a relatively new product form that has been progressively introduced in Europe. They are used daily by millions of consumers across Europe. They help consumers use just the right amount of detergent for their needs without waste; and are an effective answer to sustainability with smaller packs and important savings in terms of transport and CO₂ emissions. While they are safe when used as instructed, it is important that they are handled safely and, as any other household cleaning product, kept away from children.

Following a number of accidental exposure incidents involving small children with liquid laundry detergent capsules, A.I.S.E. developed a product stewardship programme (PSP) at the end of 2012. The programme aims to ensure safe use of this product form to be achieved through packaging modifications (i.e. reduced visibility and restricted access to the capsules); consumer education (i.e. on-pack labelling and communication campaign) and collaboration with Poison Control Centres (PCCs). To improve the effectiveness of the risk mitigation measures, a better understanding of the accident circumstances is required.

Purpose of the Study

Aim

The study aims to achieve a better understanding of the root causes and circumstances why accidental exposures occur with liquid laundry detergent capsules, especially involving young children. Both exposures to liquid laundry detergent capsules themselves, and exposures to other (non-laundry) detergent capsules, are within the scope of the study. With these findings, the effectiveness of the risk mitigation measures and consumer education campaigns that are currently implemented through A.I.S.E.'s product stewardship programme will be assessed and refined as appropriate. Furthermore, this information will also be used to help with the development of additional targeted measures as needed.

It should be noted that the purpose of this study is to collect qualitative information only. Quantitative tracking of incident enquiries (i.e. the number of calls to the PCCs) is managed via other processes.

Expected Outcome

The specific outcome expected from the accident circumstances data collection, is a data set containing a detailed description (as defined below) of the accident circumstances of exposures to detergent capsules, for a meaningful number of cases (i.e. at least several hundreds in total across all participating centres).

As a final deliverable of the project, A.I.S.E. will develop a Final Report in which the collected data are reported in an aggregated way, and in which A.I.S.E.'s interpretation is presented as well as its overall conclusions and recommendations regarding risk reduction measures.

Participation

This project is commissioned by A.I.S.E., the International Association for Soaps, Detergents and Maintenance Products. A.I.S.E. is the official representative body of this industry in Europe. Its membership totals 29 national associations across Europe and beyond and 9 direct member companies. Through this network, A.I.S.E. represents over 900 companies supplying both household and professional cleaning and maintenance products and services. These range from small and medium-sized enterprises to large multinationals.

Several Poison Control Centres across Europe will participate to the project: Dublin, Göttingen, Milan, Prague, and Utrecht. Participation of an individual PCC is considered as a bilateral agreement between that PCC and A.I.S.E.

Methodology for Data Collection

At the participating Poison Control Centres, enquiries regarding accidental exposure to detergent capsules will be specifically monitored. For each case, where possible, further follow-up will be conducted regarding the exact product involved and the circumstances under which the exposure occurred. Other potentially important aspects (e.g. regarding laundry habits, family situation, etc.) will also be included. In addition, for symptomatic

cases with moderate or severe effects, the toxicological aspects (symptoms, severity, treatment and recovery) should be included when feasible.

Data Collection Protocol

Questionnaire: A questionnaire and a data collection format (Annex) is proposed by A.I.S.E. for use as a starting point, to ensure consistency between the different participants, and homogeneity of the collected data. During the preparatory work, participating PCCs will be encouraged to exchange ideas regarding these elements, to ensure homogeneity of the process and of the collected data.

Follow-up: Usually, follow-up with the caller after the initial enquiry to the PCC will be required to collect the necessary information. This should be done soon after the initial call (e.g. typically within days). How the follow-up process is managed will depend on the applicable procedures in the individual PCCs, and on the fact whether the initial enquiry was by a medical professional or by the parent / care giver.

The actual data collection protocols, including the approach how to manage follow-up calls, are to be defined by the individual PCCs, to ensure an optimal fit with the existing work processes and resources in place at the individual centre.

Ethical Committee Review

Prior to the start of the study, each PCC will submit its data collection protocol to the centre's Ethical Committee for review and approval.

Inclusion Criteria

- All human exposures with patients of all ages and genders are to be included.
- All routes of exposure (oral, eye, skin, combined) are to be included.
- All cases with exposure to the products within scope are to be included, irrespective of whether a causal relationship between this exposure and the reported effects has been established.
- Products within scope:
 - o All unit dose detergent products contained in a soluble film (laundry, automatic dishwashing, cleaners). These products may either be entirely liquid, or partially liquid / partially solid, or entirely solid (i.e. powder-based). *To note, powder-based automatic dishwashing tablets that are individually packed in a non-soluble disposable wrapper are not within the scope - whereas powder-based automatic dishwashing tablets contained in a soluble film that is not to be removed before use, and that are not individually packed in a disposable wrapper, are within the scope.*
 - o A.I.S.E. will provide a list of brand and variant names to help the PCCs identify the relevant products in their national markets. This list will not include EAN codes, as this level of detail is not required, and this information is typically not easily traceable during a PCC enquiry. Ultimately, the decision to include a case shall be based on the PCC expert's judgment, based on the caller's description of the product.
- Consent: only cases where informed consent can be obtained shall be included.

Exclusion Criteria

- Completeness: sufficient information about the accident circumstances must be available in order to include a case. The reporting of cases with only partially completed accident circumstances information will be acceptable. However, as a minimum, the identification of the product (see further in the proposed questionnaire) and a clear description of how the accident occurred are essential.
- It is recognized that follow-up on cases reported by a medical professional, instead of directly by the parents or care givers, may be challenging. The PCC may decide, on a case-by-case basis, to exclude incident enquiries where follow-up on accident circumstances is not expected to be productive.
- The number of cases that are excluded (either because productive follow-up was not possible, or because appropriate consent was not obtained) needs to be tracked.

Cases Requiring Toxicological Follow-up

In-depth toxicological follow-up regarding the evolution of the effects, treatment, recovery - is only to be considered for cases with a PSS (Poisoning Severity Score) of 2 or higher. In principle, this follow-up should be continued until the case is resolved. No such follow-up is required for asymptomatic cases or for cases with mild, transient and spontaneously resolving symptoms.

Furthermore, toxicological follow-up is only to be progressed when this is practically feasible without disproportionate additional effort.

Data Processing

The PCC shall ensure that the patients and/or their treating doctors are adequately informed about the data collection, and shall ensure that data are only collected once informed consent by the patient has been appropriately received and documented.

Data related to the patient contact details, their treating doctor, and to the patient's consent, shall be kept internal and confidential to the PCC, and shall not be shared either with A.I.S.E. or with any of the project's partners. The PCC continues to be responsible, on an individual basis, for safe storage of the original raw data including the confidential and patient consent information.

The anonymised accident circumstances data (with any personally identifiable information removed by the PCC) will be tracked using an Excel™ spreadsheet template (which will be made available by A.I.S.E. to all participating PCCs). The data should be entered into this spreadsheet in English. These data will be made available by the PCC to A.I.S.E. for further analysis and interpretation, on a monthly basis.

Quality Control

The participating PCCs will ensure internally that the data shared with A.I.S.E. have been collected according to the implemented protocol.

Timing / Duration

Each participating PCC will initiate the data collection as soon as the Ethical Review at this PCC has been favourably completed. Consequently, there will not be a common starting date.

The data collection will run for 6 months for each participating PCC.

In case the total number of reported cases (across all participants) reaches 1500, A.I.S.E. may decide to terminate the data collection phase, for all PCCs, before the 6 month period is completed.

Use of the Results**Data aggregation and interpretation**

A.I.S.E. will receive the collected data, shared using the standard template, on a monthly basis. Ongoing, A.I.S.E. will aggregate and interpret these data in order to assess, refine existing and/or develop new product stewardship measures, as well as for the purpose of status reporting to stakeholders such as the European Commission and National Authorities.

After the end of the data collection phase, A.I.S.E. will prepare a Final Report with an overview of the collected data, an overall interpretation, and conclusions regarding the correlation between capsule / packaging aspects and accident circumstances. Prior to making this public, a draft of this Final Report will be shared with the participating PCCs. These PCCs will review and provide input on this report via a joint workshop, and will be asked for approval prior to publication.

Data ownership

At all times, during and after this project, the participating PCCs keep the full ownership of the data they collected within the scope of the study. They may further present or publish their findings in the scientific forums of their choice without any limitations, either individually or jointly with other PCCs. They may use the data for other purposes e.g. to meet the needs of local authorities.

Contracts and Compensation

This project will consist of several bilateral agreements between individual PCCs and A.I.S.E. As such there is not one single project, but rather, multiple similar projects that will run in parallel, and of which the findings will ultimately be aggregated by A.I.S.E.

A.I.S.E. offers to pay the participating PCCs a compensation for each reported case, to cover the expenses related to the additional follow-up, tracking and data processing. For PCCs not yet conducting similar work under various detergent industry contracts, this compensation is set at 100 EUR per case for the accidentology follow-up, in line with EAPCCT recommendations. For the sake of simplicity and efficiency, this standard compensation will be applied for all appropriately included cases, irrespective of the degree of completeness of the case report. Additional medical / toxicological follow-up for moderate and severe cases (PSS >= 2) will be compensated based on actual effort / time spent, up to a maximum of 100 EUR per reported case. It should be

noted that for PCCs already collecting and processing similar data, funded by industry, the incremental expenses inherent to participation to this project will be compensated, to be agreed between the individual PCC and A.I.S.E.

Compensation is also offered by A.I.S.E. to each participating centre for the preparatory work (i.e. implementation of the proposed questionnaire into an internal data collection protocol, and for reviewing and commenting on the Final Report. This compensation will be based on the actual effort / time spent, and can be up to a maximum of 5000 EUR per PCC. In addition, in case there are additional fees for Ethical Committee reviews, these will be compensated. Finally, A.I.S.E. will cover the PCC's travel expenses to participate to the final workshop (to be pre-aligned between the PCC and A.I.S.E.).

Proposed Questionnaire

The following list contains the topics for which follow-up and documentation is required. The actual language of the questionnaire is to be developed in local language by the individual PCCs. Note that language that may induce a feeling of guilt with the parents, or blame of the parent's behaviour, should be avoided.

Topic	Information required	Response options <ul style="list-style-type: none"> • Single option to be selected ○ Multiple options allowed
Occurrence of the incident	Date	[dd/mm/yy]
	Time of the day	[hh:mm]
	Location: which house	<ul style="list-style-type: none"> • At home • Grandparents • Friends • School, day care • Other
	Location: which room	<ul style="list-style-type: none"> • Laundry room • Kitchen • Bathroom • Playroom, child's room • Other
Identification of the patient (no personally identifiable information to be included!)	Age	[nn] years
	Gender	<ul style="list-style-type: none"> • M • F
Accident description	Route of exposure	<ul style="list-style-type: none"> ○ Ingestion ○ Eye ○ Skin
	How was the capsule's content released?	<ul style="list-style-type: none"> ○ Capsule leaked ○ Squeezing ○ Biting ○ Licking ○ Cutting or piercing ○ Handling with wet hands ○ Other
	Any other relevant information	Free text
Symptoms	Severity PSS (initial estimate, or final if different)	<ul style="list-style-type: none"> • 0 = Asymptomatic • 1 = Minor • 2 = Moderate • 3 = Severe
	Description of the symptoms (please select none, one, or several - as appropriate)	<ul style="list-style-type: none"> ○ vomit ○ diarrhoea ○ drooling ○ oral mucosae irritation ○ oral mucosae inflammation ○ pharyngodynia ○ dyspnea ○ cough ○ edema of the glottis ○ laryngospasm ○ bronchospasm ○ abdominal pain ○ heartburn

		<ul style="list-style-type: none"> ○ drowsiness ○ first-degree burns ○ second-degree burns ○ third-degree burns ○ itch ○ petechiae ○ cutaneous edema ○ palpebral edema ○ eye irritation ○ eye inflammation ○ conjunctivitis ○ corneal abrasion ○ impaired vision ○ photophobia ○ corneal ulcer ○ eye pain
	Any other relevant information	Free text
	Assessment of causality (best judgment based on available information)	<ul style="list-style-type: none"> • Certain • Uncertain • None
Identification of the product	Type of capsule: Purpose	<ul style="list-style-type: none"> • Laundry • Fabric conditioner • Automatic dishwashing • Cleaning product
	Type of capsule: Form	<ul style="list-style-type: none"> • Entirely liquid • Part liquid, part solid • Entirely solid (powder tablet)
	Brand and Variant name	Free text
	Packaging type	<ul style="list-style-type: none"> • Plastic Box / Tub • Bag • Carton
	Visibility of the capsules through the packaging	<ul style="list-style-type: none"> • Opaque pack (capsules not visible) • Transparent pack (capsules visible)
	Colour(s) of the capsule	<ul style="list-style-type: none"> • Transparent • White • Green • Blue • Purple • Pink • Yellow • Red • Orange • Black • Multiple colours • Other
	Colour(s) of the capsule - other information	Free text
	Any other relevant information about the packaging or the capsule	Free text
Accessibility of the product:	Where was the capsules pack	<ul style="list-style-type: none"> • In a high cabinet or shelf

	stored?	<ul style="list-style-type: none"> • Under the sink • On the washing machine • On the kitchen counter • On the floor • Unknown
	Was the capsules' pack stored in a cabinet with a child-safe lock / latch?	<ul style="list-style-type: none"> • Yes • No • Unknown • N.A. (because not in cabinet)
	Was the capsule stored in its original packaging?	<ul style="list-style-type: none"> • Yes • No • Unknown
	IF in the original packaging: Had the pack been left open or was it closed?	<ul style="list-style-type: none"> • Left open • Closed • N.A. (because not in original pack)
	IF in the original packaging: How did the child open the packaging?	Free text
	Was product ready for use (i.e. already taken out of its packaging) when the accident happened?	<ul style="list-style-type: none"> • Yes • No • Unknown
	Any other relevant information regarding the circumstances	Free text
Other information	Number of children in the household	<ul style="list-style-type: none"> • One • Two • More than two
	Any suggestions how the product might be made safer?	Free text
Toxicological aspects Only for cases with PSS >= 2 (for medical staff)	What treatment did the patient receive?	Free text
	Did the patient recover completely?	<ul style="list-style-type: none"> • Yes • No • Unknown
	How long did the recovery take?	<ul style="list-style-type: none"> • Recovery within a day • Several days, < 1 week • Up to 1 month • Longer than 1 month • Unknown
	Any other relevant information about the symptoms, the treatment, relevant medical history of the patient	Free text