ANNEX IV

CASE STUDY - DISINFECTANTS

In order to demonstrate the exposure risks and control measures for a specific product, this Annex considers the exposure risks arising from and control measures applied to the use of the product 'Bleach', containing sodium hypochlorite, by way of a case study (see Section 4.8 of the report).

Disinfectants

Sodium Hypochlorite

Introduction

The purpose of this case study is to examine in particular the specific and possibly unique reasons for increased risks of exposure arising amongst those professional users of disinfectants, by virtue of the fact that they are probably untrained, are self-employed, work alone, perform a myriad of activities at mobile work locations, are not provided with suitable control measures or protective equipment and/or not provided with adequate information, training and/or instruction to use these chemicals in a safe manner to avoid exposure and protect themselves should exposure occur.

Disinfectants have been chosen for this study, not on the basis of their toxicological severity to workers' health but because disinfectants as a group of chemicals/biocidal products are used in a wide range of workplaces and by a wide range of workers/professionals, whether trained or untrained, and irrespective of whether or not these workers fully understand the risks involved or whether they are provided with or have all the means (used in a collective manner) to protect themselves and others who may be affected should exposure occur.

While the study focuses on the smaller, possibly untrained or ill informed professional workers, who use disinfectants for their work activities, it must also be remembered that, as workers, these professionals must be protected while at work to the same degree as any other worker employed in for example a large industrial installation/factories/chemical plant/hospital etc. That is to say worker protection legislation (Framework Directive 89/839/EEC, Chemical Agent Directive 98/24/EC, Carcinogens Directive 2004/37/EC, CLP Regulation (EC) No. 1272/2008 and REACH Regulation (EC) No. 1907/2006) are all relevant to these workers, and require their protection using appropriate measures and means as determined based on a site specific risk assessment, using the information provided via the classification of any inherent toxicological properties of the chemicals together with correct and valid Safety Data Sheets/labelling, and any additional instructions or information developed by the manufacturer of the chemicals in question.

It also must be noted that these smaller professional users also have a responsibility to ensure that they themselves are safe while working and so must follow any instruction/information provided and ensure they are fully and adequately equipped to do the work safely, to protect themselves.

Lastly while these professionals are workers at work they can and often work in a manner resembling amateur/general public use of disinfectants, including where they purchase disinfectants for use. However unlike the amateur scenario of usage these workers will use larger quantities of disinfectants on a more frequent basis thus potentially increasing their risk and level of exposure over that of the amateur user.

Disinfectants

Disinfectants are biocidal chemicals or germicides used to kill or destroy microorganisms which may be present on the object or surface required to be 'clean'. However disinfectants are not effective against microbial (bacterial) spores. The process of cleaning a surface with a disinfectant is called disinfection with the aim of eliminating pathogenic microorganisms. Due to their ability to kill micro-organisms disinfectants are used in many workplace settings as well as in private homes, schools, hospitals, healthcare facilities, farms, etc, by a range of users who can include workers trained in the use of chemicals and specific work related activities, workers who may not be trained nor fully knowledgeable about the risks associated with using chemicals for work activities and others including the general public.

As disinfectants are so commonly used by many persons, there now exists a problem whereby terminology associated with cleaning and disinfection has become muddled and misused thus allowing for misinterpretation of what is being required and what is the best method of achieving the desired result i.e. disinfectants can sometimes be used in situations where in fact cleaning with soap and water is the required and most suitable method to achieve the level of cleanliness necessary. Below are some terms which unfortunately are often misused, not wholly understood by persons, interchanged and/or misinterpreted thus potentially leading to situations where disinfectants can and are used unnecessarily or inappropriately.

Disinfectant: *antimicrobial agents used to destroy microorganisms that exist/live on inanimate objects or surfaces. It is not effective against bacterial spores. Disinfectants are not used to sterilise as there are some bacteria and viruses which are resistant to disinfectants*

Disinfection: *process that eliminates many or all pathogenic organisms, with the exception of bacterial spores.*

Sanitise: *is to remove dirt and germs from surfaces/objects, through washing and cleaning but not to the level of disinfection. Sanitisers are used to reduce but not necessarily eliminate all bacteria i.e. reduce to a level considered safe as determined by public health requirements.*

Antiseptic: *similar to disinfectant but is applied to living tissue e.g. skin/mucous membranes etc with a view to killing microorganisms that can be present on the tissue. Antiseptics should not be used on inanimate objects or surfaces.*

Clean(ing): *involves the physical removal of foreign material e.g. dirt, soil, dust, organic secretions etc. It is accomplished using soaps/detergents and water together with physical effort i.e. scrubbing. brushing rather than wiping down a surface.*

Sterilisation: *is the complete elimination or destruction of all forms of microorganisms*

About Disinfectants

There is no single universal disinfectant which will kill all pathogenic microorganisms. Therefore the selection of the most appropriate disinfectant for the required result is extremely important. Unlike sanitisers, disinfectants are normally used at much higher concentrations and have a longer contact time (left on the surface) in order to be effective.

The choice of a disinfectant depends on the situation/required result/surface or item to be disinfected and the risk of specific organisms being present. Some disinfectant have a wide spectrum of effectiveness in that they can kill many different types of microorganisms, while others are more limited or specific in the organisms they kill but are selected/preferred because, as disinfectants, they are non-corrosive and so will not damage the equipment being disinfected, are non-toxic to humans etc.

For the purposes of this case study disinfectants are considered within the broad spectrum of effectiveness which are generally those selected by the professional users who may be untrained, unaware of the risks from exposure and/or may not be equipped or protected against possible exposure, while working with such disinfectants.

The active ingredient constituent/component of the disinfectant product provides the product with its ability to disinfect/kill microorganisms. However it is also this active ingredient which can be harmful to man and/or the environment should exposure occur while using the product.

The concentration of active ingredients present in products available for general disinfection purposes is relatively low i.e. normally up to 5% but could, on occasion, be as high as 10%. However more importantly is the information available to users regarding the correct dilution/strength to make a product for actual usage. This information must be clear and understandable and worded to ensure that users know it is critical to follow these instructions completely with no variations. Also where there is a risk to the safety of the user due to incompatible substances when mixed with the disinfectant, then this must information must be provided early on and worded in manner which will be understood and followed by the user on all occasions, irrespective of location or work activity being performed.

Disinfectants as Biocidal Products

The Biocidal Products Regulation (EU) No. 528/2012 aims to improve the internal functioning of the internal market for biocidal products whilst providing a high level of protection for humans, animals and the environment. All the products types under the previous (now repealed) Biocidal products Directive 98/8/EC are now within the scope of the Biocidal Products Regulation, with the exception of former Product Type 20 relating to preservatives for food and feedstock.

Biocidal Products are defined as any substance or mixture, including *in-situ* generated active substances, in the form in which they are supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

In addition, this biocidal product definition covers situations where a substance or a mixture. generated from a substance or a mixture not covered by the first intent is used for the purpose of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;

- e.g. a surface disinfectant with a proven biocidal claim containing sodium hypochlorite;
- e.g. the combination of TAED and sodium percarbonate forming peracetic acid for chemical disinfection (product intended to be sold as a biocide carrying a biocidal claim);
- e.g. (Second intent) the generation of sodium hypochlorite on-site and used for the disinfection of the premises1.

While there are 22 Products Types coming under the BPR, divided into 4 Main Groups i.e. Disinfectants, Preservatives, Pest Control and Other Biocidal Products, it is Group 1 dealing with biocides as disinfectant which is of interest with respect to this case study. It should be noted that some of the active ingredients included in disinfectant products types can also be found or included in other products listed in the BPR. However in these cases, while the actives may provide a disinfection ability the primary function of the product is otherwise e.g. as a preservative and so are not being considering within the context of this case study.

Group 1 - includes disinfectants used for human hygiene (PT1), disinfectants and algaecides not intended for direct application to humans or animals (PT2), veterinary hygiene (PT3), food and feed area (PT4) and drinking water (PT5).

For the purpose of this case study and taking into account the level of professional user under consideration i.e. small businesses (catering/food/kitchens etc), untrained caretaker/janitorial/cleaners, self employed persons using disinfectants as part of their work activities, farmers etc., then the primary disinfectant categories of interest relate to disinfectants used to clean surfaces, equipment (large/small) including utensils, walls, floors, toilets, housing, containers, storage units etc i.e. PT 2, 3, and 4.

Types of Disinfectants available and used in workplaces

Alcohols
Commonly used as antiseptics in the healthcare setting. They can cause the deterioration of materials such as rubber and plastic. As they evaporate rapidly they can evaporate off a surface and so are for extended exposure purpose the best method of use is immersion. They irritate the skin, may not penetrate organic matter, are flammable and quite expensive. While alcohols are used as disinfectants in specific situations they are not generally used as an all purpose surface disinfectant.

Iodophors
Iodophors are used as both antiseptics and disinfectants. An iodophor is a combination of iodine and a solubilising carrier, resulting in a reservoir which can release small amounts of free iodine in aqueous solutions. Iodophors are not suitable as surface disinfectants as the concentration of free iodine is less. Iodophors are used generally for the disinfection of blood culture bottles and medical equipment. Iodine based disinfectants are available (with a higher

[1] A.I.S.E.; BRP in Brief, Guidance for A.I.S.E. members, Version 1.0 - November, 2013

amount of free iodine). The disinfective ability of iodine can be neutralised in the presence of organic matter. Iodophors should be made up in cold water to prevent breakdown of the disinfectant.

Quaternary Ammonium Compounds
Quaternary ammonium compounds are widely used as disinfectants in ordinary environmental situations where disinfection of non-critical surfaces is required e.g. floors, furniture, walls etc. They can however become less effective if used with high water hardness solutions and where some wipes or cloths/cotton or pads can absorb the active ingredients. Gram negative bacteria have been found to survive or grow in these preparations.

Phenolics
Phenolics are derivatives of phenol. They are less affected regarding neutralisation in the presence of organic matter. Phenolics are used for disinfection in hospitals e.g. laboratory surfaces and non-critical medical items. Phenolics can be present in some household disinfectants as well as mouthwashes and soap etc. Phenolic disinfectants are generally safe but prolonged exposure can cause irritation. They can be absorbed by porous materials/surfaces leaving a residual presence for further/future exposure to persons. Caution is advised when using phenolics for disinfection in environments/settings where there are vulnerable persons e.g. infants/nurseries/childcare facilities etc.

Hypochlorites
Hypochlorites are the most widely used chlorine disinfectants and are available in liquid or solid form. The most common and universally used form is household bleach liquid which contains sodium hypochlorite as its active ingredient. It has a broad spectrum of antimicrobial activity, is not affected by water hardness, is relatively inexpensive and fast acting. However it can have a corrosive effect when used on metal surfaces, cause discolouration of fabrics and materials (i.e. 'bleaching') and can be deactivated/neutralised in the presence of organic matter. Household bleach is recommended for use in most hospitals and associated healthcare facilities as well as being the agent of choice for disinfection of surface in the food preparation sector. Additionally bleach is use as disinfectant in most premises where there are bathrooms, toilets and other sanitary facilities and in veterinary premises as a general use disinfectant. The effectiveness of bleach can lessen when pH increases. Bleach should be made up in cold water to prevent breakdown of the disinfectant.

Other Higher Level disinfectants

Hydrogen peroxide - Used as an antiseptic and for post-surgery site activities. Stabilised hydrogen peroxide can be used as a disinfectant for surfaces and can be blended with other disinfectants to provide a high level of disinfectant.

Glutaraldehyde - aldehydes have a wide germicidal spectrum of activity. They can be used as disinfectants or sterilant in both liquid and gaseous forms. Glutaraldehyde is a potent and highly toxic disinfectant which is used under controlled and very specific conditions by trained personnel and with adequate and appropriate control measures in place.

Formaldehyde - used as a disinfectant and sterilant in both liquid and gaseous form. Can be obtained as a water based solution called formalin. Formaldehyde is toxic and carcinogenic and would not be used generally as a surface disinfectant in general environments or settings. It should only be used under strict conditions of control, for specific activities and by trained personnel.

Peracetic acid - is used in automated machines for sterilisation of instruments. It has a rapid action against all microorganisms and is not deactivated in the presence of organic matter. However it does corrode copper, brass, bronze, steel and galvanised iron. It is unstable, particularly when diluted. It would not be the preferred disinfectant for surface disinfection.

Sodium Hypochlorite

For this case study we are examining disinfectants which are used for general surface disinfection and used by smaller, possibly untrained, professionals and others. Therefore Bleach i.e. sodium hypochlorite, has been selected. The reasons for this selection include:

- Widely used;
- Familiar to all persons and the general public;
- Known as a disinfectant;
- Easily available (different brands);
- Easy to use as a liquid;
- Can be used universally in a wide range of locations;
- Can be used for numerous activities.

In fact bleach is so commonly known that the term bleach can often be applied to disinfectants which in fact do not contain the active ingredient of sodium hypochlorite i.e. as familiar as *'hoover', 'biro', 'JCB'* etc. However this familiarity can also lead to problems and an increased risk of exposure due to an element of complacency about the product which in fact is not an innocuous substance but a chemical agent with a biocidal function.

It is can be used in virtually all workplaces in varying quantities, especially where there are toilets and restrooms or other sanitary facilities, hard surfaces on which food is handled, facilities where a large number of people are present, where animals are present or have access, care facilities, residential homes, schools, farms etc i.e. any place where there is a need to ensure persons cannot be adversely affected due to the possible presence of microorganisms on surfaces to which they can be in contact and thus exposed to pathogens. This is particularly true for premises dealing with persons deemed to be vulnerable e.g. infants, the elderly, the sick etc.

Bleach

Generally available bleach products contain ca 5% active sodium hypochlorite, with some commercial brands listing up to 10%. Bleach sold for specific sectoral use e.g. the dairy sector can contain between 10-20% sodium hypochlorite. Chlorinated compounds such as sodium hypochlorite when diluted in water form hypochlorous acid which is extremely effective against many type of microorganisms including bacteria, fungi and viruses.

Bleach is an excellent disinfectant but is a poor cleaner, therefore for bleach to be successful it is essential that the surfaces are firstly cleaned i.e. pre-cleaned and any dirt, soil matter removal etc as this can diminish the efficacy of the disinfectant.

EU Classification

There is a harmonised EU classification for sodium hypochlorite as outlined by the CLP Regulation. Where a harmonised classification is set this classification is mandatory (as a minimum) noting that some manufacturers may choose to self classify to a higher level.

Sodium Hypochlorite Classification

CAS No: 7681-52-9
EC No: 231-668-3
Index No: 017-011-00-1
REACH No.: 01-2119488154-34

(a) CLP Regulation 1272/2008
Skin Corr. 1B; H314 (Causes severe skin burns and eye damage)
Aquatic Acute 1; (Very toxic to aquatic life)
EUH031 (Contact with acids liberates toxic gas (specific conc. limit >=5%)

(b) Directive 67/548/EEC
C; R34 (Corrosive; Causes burns)
R31 (Contact with acids liberates toxic gas (Conc. limit >=5%)
N; R50 (Dangerous for the environment; Very toxic to aquatic organisms)

For Bleach, containing sodium hypochlorite as a mixture, requires that this product is classified in accordance with the CLP Regulation by June 2015. Prior to this deadline safety data sheets can include the dual classification for the product but should include the CLP classification for any hazardous individual components of the product including, in this case, sodium hypochlorite.

Once classification of the product is re-considered from June 2015, dependent on the percentage of sodium hypochlorite present in the mixture/product may and probably will require a change to the existing classification of the product or cause the product to be classified where previously this was not required. These changes reflect the rules for classification as set down in the CLP Regulation. For example:

Where an ingredient is classified as Skin Corr 1B and is present in the product at >=5%, then the product also is thus classified.
Where an ingredient is classified as Skin Corr 1B and is present in the product at >=1% - <5%, then the product is classified as a Skin Irritant.
Where an ingredient is classified for eyes (re skin corr 1B) and is present in the product at >=3%, then the product is classified as a Eye Damage 1.
Where the ingredient is classified for eyes (re skin corr 1B) and is present in the product at >=1 - <3%, then the product is classified as Eye Irrit 2.

Such changes will require the revision of product safety data sheets including the associated information on protection and control measures so as to ensure that the information provided, for the benefit of the user of the product, is still valid and appropriate for product as classified and that when followed fully will ensure that users can work with the product in a safe manner.

It should be noted that where Industry/individual manufactures opt to perform a self-classification which is severer than the mandatory harmonised EU classification and supplies this classification/SDS to downstream customers then this information should be used for the purposes of developing the end-product SDS, including any associated protective and control measures required based on

this classification, unless the downstream should want to submit his own classification.

Sodium Hypochlorite - Toxicology

Sodium hypochlorite is toxic due to the hypochlorite moiety which forms when sodium hypochlorite is dissolved in water in alkaline conditions. Hypochlorous acid generates superoxide radicals that cause oxidative injury and cell death.

Symptoms of sodium hypochlorite exposure may be immediate or can be delayed for a number of hours.

Ingestion - The LD_{50} (rat) was calculated to 290mg/kg for oral route and 33.3mg/kg for intravenous route.

In Man, at low concentrations (up to 10%) sodium hypochlorite is a mild to moderate irritant. Ingestion of small amounts is not expected to cause severe of permanent damage. At concentrations greater than 10% it is corrosive with the PH thought to be 12.5.

In a worst case scenario ingestion of small amounts (e.g. 200ml (adults)/50ml (children)) (conc. up to 10%) could cause burns to the mouth, throat, oesophagus and stomach, pharyngeal pain and inflammation, GI irritation, nausea and vomiting. Where larger amounts are ingested (e.g. 300ml (adults)/100ml (children)) or where the concentration is greater than 10% then corrosive oesophagitis, haematemesis, abdominal and retrosternal pain, diarrhoea and, in some cases, malena and metabolic acidosis may occur.

Most children who ingest bleach swallow only small amounts and experience vomiting and GI irritation. Aspiration of sodium hypochlorite or of contaminated vomit can, as a secondary pulmonary exposure, can lead to pulmonary complications such as Acute Respiratory Distress Syndrome (ARDS) i.e. a lung condition that can lead to low oxygen levels in the blood, which can cause oxygen deprivation of essential organs in the body.

Skin/Eye
Sodium hypochlorite is corrosive and may irritate or cause burning pain, inflammation and blisters. Damage to the skin can develop over time.

At concentrations of less than 10% conc. can cause mild irritation and temporary discomfort where eyes are washed immediately following exposure. Where washing does not occur immediately then the irritant effect is more severe and prolonged. Where the concentrations are in excess of 10% then exposure to the product can cause pain, blepharospasm, lacrimation, conjunctivitis. necrosis and chemosis of the cornea, iritis, cataract formation and retinitis.

Inhalation
In general, intoxication via inhalation of sodium hypochlorite vapours is extremely rare as chlorine gas is not released by bleach solutions in appreciable amounts under normal conditions (of use/as per instructions). However even at low concentrations people with asthma or other respiratory disorders/breathing problems could experience serious symptoms after bleach exposure.

Where sodium hypochlorite is mixed with acids, then chlorine gas is released. However the concentration of chlorine gas released should not be sufficient to causes adverse health effects. Given a worst case scenario, where, sufficient chlorine gas is released due to this mixing with acids, then those exposed will

have immediate burning of the throat and lungs, eyes and nose irritation, chest tightness, coughing, sore throat, wheezing and dyspnoea. In severer cases, bronchospasm, pneumonitis, upper airway oedema, pulmonary oedema or oedema of the glottis may develop.

Mixing of sodium hypochlorite with ammonia-based solutions can result in the formation of monochloramine and dichloramine, both of which are respiratory irritants.

In most cases respiratory irritation occurs immediately, followed by a latent period of 5-15 mins, after which time breathlessness and bronchospasm may occur. However less common but also a possibility is that pulmonary damage could lead to long-tern reactive airways dysfunction syndrome (RADS).

Carcinogencity
Sodium hypochlorite is not thought to cause cancer. IARC have classified it/hypochlorite salts as Group 3 i.e. not classifiable with respect to carcinogenic potential in humans.

Mutagenicity
While sodium hypochlorite has some mutagenic potential in both bacterial and mammalian cells *in vitro,* there is no evidence for similar activity *in vivo,* and as such therefore sodium hypochlorite is not thought to be mutagenic.

Reproductive Toxicity
Experimental data suggests that hypochlorite does not have any adverse effect on the reproductive system. Sodium hypochlorite is not thought to cause damage to the unborn child.

Toxicological summary

While sodium hypochlorite is not a highly toxic chemical and does not cause long-term effects as such as cancer or reproductive toxicity, the adverse health effects it can cause, following exposure, can be immediate, severe and can be experienced by those workers using the chemical/product and by others including children, other vulnerable persons and animals, who come in contact with/be exposed to or inadvertently ingest the chemical/product/disinfectant.

From an occupational perspective the primary exposure routes of concern are inhalation, then dermal and finally ingestion. However as this product is available in a wide range of premises and used by a range of trained and untrained professionals the route of ingestion takes on a higher significance, in particular, where the professional user may decant the disinfectant to other smaller containers, without fully transferring the label information etc. or may store the product(s) in an insecure manner. Premises such as school, farms, residential care homes, recreational facilities, childcare facilities, nurseries etc can have disinfectants present/stored/handled in the vicinity of vulnerable persons who, together with the actual professional user of the disinfectant, could potentially be exposed via, inhalation, dermal contact and ingestion.

Safety

Notwithstanding the toxicological properties of a disinfectant which can cause adverse health effects should exposure occur, where sodium hypochlorite is not

handled correctly i.e. mixed with certain incompatible substances then additional dangers to health arise relating to the by-products produced by this bad mix.

- Emits toxic fumes of chlorine and sodium oxide when heated to decomposition or upon contact with acids.

Chlorine gas exposure, even at low levels, will irritate the eyes, nose and throat, cause coughing and breathing problems. Higher levels of exposure can cause chest pain, more severe breathing difficulties, vomiting, pneumonia and fluid in the lungs. Very high levels can be fatal. Chlorine is absorbed through the skin, resulting in pain, inflammation, swelling, and blistering.

Note: Children exposed to the same levels of gases as adults may receive a larger dose because they have a greater lung surface area:body weight ratios and higher minute volume:weight ratios. Children may be more vulnerable to corrosive agents than adults because of the smaller diameter of their airways. In addition, they may be exposed to higher levels than adults in the same location because of their short stature and the higher levels of chlorine found nearer to the ground (i.e. chlorine is heavier than air and so settles in lower/low lying areas, closer to the ground).

- Sodium hypochlorite is incompatible with strong acids, amines and ammonia.

When bleach is mixed with ammonia, toxic gases called chloramines, which are explosive, are produced. Exposure to chloramine gases can cause coughing, shortness of breath, chest pain, wheezing, nausea, watery eyes, irritation to the throat, nose and eyes, pneumonia and fluid in the lungs.

- Sodium hypochlorite on contact with metals hydrogen may evolve.

- Hypochlorites react with urea to form nitrogen trichloride, which explodes spontaneously in air.

- Contact of hypochlorite with ammonium salts and acid leads to the formation of nitrogen trichloride.

- Reaction with formic acid becomes explosive.

In summary, considering the professional user for this case study, safety requirements when using bleach are extremely important, in particular, the need to provide clear instructions regarding incompatible substances, using recognisable names rather than chemical/IUPAC terminological, when referring to substances which should not be mixed with bleach. The facts are:

- Never mix bleach and ammonia;
- Never mix bleach and acids;
- Never mix or use two drain cleaners together; and
- Never use one drain cleaner immediately after another one.

Accidental poisonings

Accidents can and do occur when using bleach, whether the exposure is to the user of the disinfectant or another person or child in the vicinity of the substance being used or due to where and how the product is stored. It is estimated that ca

3,300 accidents, needing hospital treatment, caused by sodium hypochlorite solutions, occur each year in British home (RoSPA, 2002)[2].
While the focus of this case study is occupational exposure to professional (smaller) users, considering the locations where these workers may be employed e.g. private homes, schools, nurseries, healthcare facilities, farms etc i.e. places where others, including children and toddlers may be present, if a proper system of work is not employed or the possibility of exposure occurs then these other persons can potentially be affected also.

Looking at the data from the Annual Report (2002)[3], National Poisons Information Centre, Ireland, provides some insight into the significance of poisonings which can occur.

- Of the total number of poisonings 62.2% were accidental poisonings;
- 92.2% of all enquires made to the Centre related to cases of poisonings;
- 44.4% of those enquires related to children under 10 years of age;
- The majority of cases involving household products/cosmetics/personal hygiene products and plants were children under 10years of age.
- Of the 1,553 cases involving household products specifically, 1,135 were children under 10 years of age.
- Of the 1,135 cases in children, 989 case were in children between the age of 1 and 4 years i.e. toddler stage.

In addition information produced relating to injuries treated in Emergency Departments in the US (1990-2006)[4], indicate that the product most commonly associated with injury was bleach (37.1%). Children 1 to 3 years of age accounted for 72.0% of cases. The primary mechanism of injury was ingestion (62.7%). The most common source or container was spray-bottles (40.1%).

Previous research and recommendations from the American Academy of Pediatrics and others have suggested storing poisonous substances in locked cabinets, out of sight and reach of children, buying products with child-resistant packaging, keeping products in their original containers, and properly disposing of leftover or unused products. Additionally this article recommends the development of educational programmes and materials, regarding household cleaning product-related injury prevention, specifically addressing the use and storage of spray bottles.

Likewise, Mrazova, Navratil & Pelclova (2012)[5], state that cleaning products are responsible for many accidental exposures among children and adults and depending on the composition, they may cause corrosive damage. Their conclusions included findings whereby, acute exposure to cleaning products and adults constitute a major problem for healthcare specialists worldwide. These injuries occur mostly by accident, with the accidental ingestion of cleaning products being quite common. They conclude that careless storage and improper safeguarding of these chemicals/products is the single reason for accidental ingestion. They also recommend caretakers' education with respect to intoxication prevention.

Overall, where and how small professional users use disinfectants can impact on themselves but also on others, particularly children in the vicinity of either the

[2] Home and Leisure Accidents Statistics, Royal Society for the Prevention Of Accidents (RoSPA), 2002
[3] Annual Report, 2002; National Poisons Information Centre, Beaumont Hospital, D.9, Ireland
[4] Household Cleaning Product-Related Injuries Treated in US Emergency Departments in 1990-2006; McKenzie, L.B.; et al., Pediatrics Vol. 126 No. 3, September 1, 2010
[5] Consequences of Ingestions of Potentially Corrosive Cleaning Products, One Year Follow-Up; Mrazova,K., Navratil, T., and Pelclova, D., Int. J. Electrchem. Sci., 7 (2012) 1734-1748

work activity itself or the area where these professionals store their products. As stated, workers have a responsibility to protect themselves and others who could be adversely affected by their work activity.

Consumers - Risk of Exposure to Sodium Hypochlorite

While this case study has primarily been focussing on workers, in particular those professional workers who may be operating as self-employed or untrained, in small operations without the support structure normally available in larger workplaces, the risk of exposure and the uses of disinfectants containing sodium hypochlorite, are analogous to the risks and potential for exposure that can occur to consumers/the general public who also use these products.

Reasons for the similarity in exposure potential

- Consumers use bleach to disinfectant surfaces in the same way as professional users.
- Consumers buy many of the same products used by these professional users.
- Consumers receive the same information on the label regarding instructions and use and any risks associated with contact/exposure to the products as do professional users.
- Consumers use the same manner and means of applying the product to the surfaces for disinfection as these professional users.
- Consumers are working in similar environments as these smaller professional users i.e. private dwelling/homes.
- Consumers are not being monitored or supervised when using these products.
- Consumers will not have received specific chemical agents training, in particular regarding the risks when handling/using/storing and disposing of hazardous products.

However there also exists the possibility of differences in the risks arising from potential exposure between these two distinct categories of user i.e. the consumer and the smaller professional user.

(i) Smaller professional users, while maybe not trained in the specifics of chemical agents, will have received some form of training regarding their particular skills and tasks, and as such will be familiar with the need to follow instructions/dilutions/quantities etc. Such professional users should/must have certain items of personal protective equipment available and with them when doing their work e.g. gloves/masks/coveralls/wipes etc. Additionally, while maybe not trained specifically, such workers, including the self-employed, will be familiar with health and safety requirements as the arise with respect to the need to have a safety statement, the concept of risk assessing work activities, thinking through operating procedures, and what materials/chemicals/substances will be required for a specific work activity. To this end they will, at some level, have considered exposure/use and health and safety matters. Also as a worker at work, using a hazardous substance/product, infers that all relevant work protection legislation applies. Lastly and most importantly such professional users should and must have been given a valid safety data sheet (SDS) for any hazardous substance or product they purchase and intend to use for work. The SDS contains essential information regarding control and protection measures recommended etc.

(ii) The consumer, while using the products for the same purpose and in the same manner, will not (a) be supplied with the same level of information (b) will not have the direct protection of the worker protection legislation to ensure their safety health and welfare at work.

To this end consumers or members of the public will only receive a safety data sheet if they know to request this document from the vendor/supplier. This rarely if ever happens. By not having the valid SDS means the consumer is not informed regarding the detailed information relating to storage/handling/use/disposal, exposure risk and recommended controls and protective equipment required, together with other information regarding broader risks and routes of exposure/emergency scenarios i.e. information in an SDS in addition to the formal classification of the product based on CLP criteria alone.

There is no means of ensuring that consumers will follow the dilution and use instructions which are contained on the packaging of the product. In fact given observed human behaviour (outside the workplace and working frame of mind), consumers are apt to use more of a product that specified, or use a stronger more concentrated form of the product than specified, on the presumption that this 'will do the job faster' or ' this will do the job better'.

Regarding legislative requirements/obligations and protection measures, these apply to employers and employees i.e. professional users of hazardous substances or mixtures and not to members of the public. While the means or methods of protection will be the same for a professional user and a consumer when using the same product under the same or similar conditions of use, the requirements to ensure that a consumer is protected/trained and provided with the necessary protective equipment etc does not fall within in the scope of that legislation.

In reality many of the products used by smaller professional users are the same as those used by consumers in a private capacity. Therefore the adverse effects which can occur should exposure happen are the same for both the professional user and the consumer, in particular noting that the composition and concentration of the ingredients in many of these products are the same irrespective of whether it is being used by a professional user or by a member of the public.

Safety Data Sheets (SDSs)

For the purposes of this case study we have examined a representative number i.e. ten/10 EU sourced SDSs, that were readily available relating to Bleach/disinfectant containing sodium hypochlorite. Set out below are some overall findings regarding these SDSs.

Firstly it should be noted that 9 of the 10 SDS documents are very recent and so should be up to date, in EU format and aware of the duality required between substances/mixtures and Directive 67/548/EEC & CLP Regulation 1272/2008. 1 SDS (2007), 1 SDS (2011), 2 SDSs (2012), 3 SDSs (2013) and 3 SDSs (2014).

All SDSs relate to bleach/disinfectant.
2 of 10 specified 'For professional Use Only'.
1 had the term 'professional' in the title/name' but did not specify this product was to be used only by professionals.
7 of the 10 approximated the EU format required - with room for improvement.

2 had no CLP classification for the individual ingredient (sodium hypochlorite)
1 was wholly inadequate.
Of the 10 SDSs the concentrations listed were: 16% (professional use specified); 1-10% (professional use specified); 1-5%; 13-16%; <5%; 14-15%; 1-5%; 10-25%; <12% and 10-20%.
Regarding classification:
9 had the correct EU classification for Sodium hypochlorite in accordance with the substances Directive (67/548/EEC). 7 had the correct classification for sodium hypochlorite in accordance with the CLP Regulation, with 3 of these 7 SDS providing additional/more than the mandatory harmonised classification i.e. as per Industry self classification.

8 of the 10 SDSs listed an emergency contact, with 2 of these 8 giving contact details for the relevant National Poison Information Service or Centre.

Regarding the level of detail/information provided:

(a) *Section - First Aid measures* - 6 reasonable, 2 did not mention the important fact of not inducing vomit (re corrosivity) and 1 mentioned do not induce vomiting when person is unconscious thus implying it would be correct to induce vomiting if person is conscious - this is not the case.

(b) *Section 6 - Accidental Release measures* - All 10 lacked detail. Many made no mention of spills or distinguished between large/small spills. Few mentioned the means to contain or absorb a spill.

(c) *Section 7 - Handling and Storage* - Overall this section provided inadequate information especially regarding the precautions necessary for safe handling. One SDS referred the reader to Section 10 for information on incompatible materials, yet when you read Section 10 - it states 'not applicable'. Others listed only acids as incompatible materials, with no mention of ammonia or mixing with other cleaning agents etc. 2 stated that incompatible materials were not an issue. Finally one mentioned avoid ignition sources and sunlight but no mention of other incompatible materials such as acids, ammonia etc.

(d) *Section 8 - Exposure Controls/Personal Protection* - Only 2 provided detailed information. Majority gave insufficient/inadequate information with no detail or specifics. 1 mentioned that measures were not required and not applicable.

(e) *Section 9 - Physical and Chemical properties* - This section lacked detail, provided little information. Many SDSs referred to the fact that testing had not been done on the mixture. However data gaps such as PH, boiling point, flammability, solubility, viscosity etc could have been provided.

(f) *Section 10 - Stability and reactivity* - Point 10.5 relates to 'Incompatible Materials', yet 1 stated 'not applicable', 6 referred to the range of incompatible materials, 3 made no mention of ammonia, 1 made no mention of acids, and 1 said no incompatible materials were known.

(g) *Sections 11 & 12 - Toxicological & Ecological Information* - the data in both these sections was limited or non-existent, with many referring to the fact that testing had not been performed on the mixture. Others related it to the classification assigned without providing any test results i.e. met or did not meet the criteria for classification only.

(h) *Section 13 - Disposal considerations* - Only 1 referred to the PPE when disposing of material. 2 mentioned the need to avoid release to the environment. Some mentioned care required when disposing of empty containers. The majority only referred to the need to comply with local Regulations. However for the professional users we are considering in this case study this information is wholly inadequate and will not be followed or understood - even to the point of how to find out what the local requirements are.

(i) *Section 14 - Transport information* - 5 of the 10 SDSs referred to dangerous for environment and/or marine. 6 referred to corrosivity. Most stated 'not classified', 'not applicable' with no other data or clarification.

(j) *Sections 15 & 16 - Regulatory & Other Information* - 6 of the 10 SDS failed to mention or refer to the CLP Regulation. Many were not in the required format and 1 was totally incorrect. Some only provided the risk/safety phrase explanations, others only provided the CLP version i.e. the hazard/precautionary explanations, while the remainder provided both versions (as recommended until June 2015).

Discussion about SDSs and professional users

The professional users of interest in this case will rely specifically on the information both on the label of a product and the information contained in the associated SDS. To this end it is vital that the information is sufficient and provided in an understandable and user friendly way for these workers so as to ensure that, by following the information and instructions therein, they can work safely and do not adversely affect others in the vicinity of their work.

However, even though the SDSs reviewed above are recently revised, the information is incomplete, lacks detail and is not user friendly for those who may not be specifically trained, maybe working alone or at mobile locations. The information in certain sections of the same document proved to be inconsistent. Given that these SDS refer to Bleach (containing sodium hypochlorite ranging between 1 - 25% concentration) the level of information varied and on occasion proved to be contradictory between different documents. Considering only two of the 10 SDSs specified 'For professional Use Only' means these products can be purchased and used by a range of persons including professionals users. Depending on what product selected and which SDS provided (if any) then, the level/quality of information provided will therefore also vary.

While 8 of the SDSs did not indicate for professional use, if these products are used by smaller, possibly untrained, professional users, the quantity and frequency of use can potentially be greater than that of the private home owner.

As noted above children are at particular risk from ingestion of such products. While the smaller professional user may not be working directly with children, there is a foreseeable and real chance that these workers are employed in premises where children (including toddlers) are present. Therefore it is essential that the storage/handling and disposal of product/product containers is understood and performed correctly.

Regarding the information contained in an SDS (16 Sections), for these professional users, certain sections are of particular relevance and must provide enough and detailed information for them to operate and work safely. Example:

- Section 1 - providing the name, various identifiers and emergency contact details;
- Sections 2 & 3 - providing information on the classification and identified hazards of the products and the individual hazardous ingredients;
- Section 4 - providing first-aid measures for each possible route of exposure;
- Section 6 - what to do should there be an accidental release/spill and how to contain same;
- Section 7 - provides essential information on handling and storage, including any incompatible substances which should be avoided;
- Section 8 - provides information on controlling exposure including what PPE (and RPE) may be required. This information should be specific and detailed i.e. avoid generic statements.
- Section 13 - provides information regarding how to dispose of the product, any residues and empty containers. This information should be as specific as possible i.e. avoid generic statements.
- Section 15 & 16 - should provide the wording for any risk/safety phrases and hazard/precautionary statements used in the document and where appropriate a glossary of any terms or abbreviations used throughout so as to ease understanding for the reader.

Additionally, where products are not specifically indicated for professional users only, and the product itself is not classified as hazardous, then, when professional users purchase these products there is no obligation to provide the SDS to that person. For consumers such SDSs can be provided or made available on request. This being the case there arises the situation where these professional users must know to ask for the SDS at the time of purchase. This is assuming they have received training and thus know to ask for the SDS.

Finally as a recommendation specifically regarding the SDSs for this product, we would emphasis the need to elaborate and provided far greater detail regarding what materials/other substances are incompatible and explain in more detail the risk should mis-mixing occur. We would suggest that this information should use general names/recognisable names for these users to understand the risk fully. Based on the reported accidents (occupational and otherwise) the risk and adverse effects when this product is mis-mixed are a reality and provide annual statistics of such events as proof.

Conclusions

Professional users of disinfectant can be exposed to these chemicals while using them for work activities. However where professional users are employed in settings such as manufacturing, large food and beverage production facilities, hospitals, i.e. workplaces with a formalised structure, management systems, supervision capabilities etc., together with fixed engineering controls and readily available prevention/control measures and personal protective equipment, then those professional users can work safely with such chemical in accordance with the requirements and specifications set out in existing worker protection legislation.

However notwithstanding those professional users above, there are many other professional users who are not so well protected by virtue of their circumstances of work and whether or not they have been trained/informed or whether their employers are fully informed of employers' responsibilities to all their workers, including the materials and equipment required to be used on-site for the purpose of work activities. For example, the primary focus for a school is education and

the children being educated therein. However also present are cleaners, janitors, caretakers and probably, on a more casual basis, persons employed for specific tasks which arise e.g. drain clearage, pluming related issues etc. These workers are entitled and should be protected to the same degree, and in accordance with the same worker protection legislation as those working in manufacturing and industrial sectors. However the message is not getting through to (a) these employers, and (b) the professional users themselves (especially if self-employed).

Finally, by law manufactures of chemical have a responsibility regarding the chemicals they produce and place on the market. This responsibility extends to those using their substances and/or their substances for inclusion in products. In other words manufacturers are obliged to communicate down the supply chain. Also, and mostly because of REACH, communication also goes up the supply chain from customers and downstream users to their suppliers and further up until the information is communicated and acquired by the relevant manufacture. Manufacturers therefore are aware of the variety of uses and environmental settings to which their chemicals are being applied. This information should be used and reflected when compiling SDSs so as to make the information practical and useable down the supply chain.

Recommendations

1) Starting with manufactures, the requirement to communicate is not new and has always been required via the supply of a Safety Data Sheet and the label. Knowing there are professional users who may be handling their substances/products without adequate or any training and education and possibly without suitable protection, then consideration **must** be given, by those placing the substance on the market, to endeavour to provide essential information in a clear and linguistically focussed manner to attract and encourage these professional users to take note and comply with the information provided.

2) The information provided in SDSs must be clear, understandable and specific regarding. Currently, even when an SDS complies with the EU required format, the information provided in generic and does not assist the type of smaller professional user being considered here. Overall the quality of current SDSs requires improvement in the majority of cases. Additionally avoid contradictory information. Where mis-information arises from the supplier it will invariably be used and often reproduced (without amendment) in the SDS associated with the product containing that substance.

3) When considering these smaller professional users, it is important that, in particular, sections of the SDS dealing with issues such as emergencies, accidental spills, storage, handling, disposal and exposure controls are clear, comprehensible and can, in reality, be practically followed in all workplace scenarios. Often times this is the only information available to such professional users, on the assumption they have been provided with or have actually asked for/acquired a copy of the SDS.

4) Training of/for these professional is an issue of concern. There is no single means of addressing this concern successfully in order to safeguard all persons fitting into this category of worker, which therefore requires to be approached on a sectoral basis, specific to the product type. In the case of disinfectants this would require tailored approached to those working within agriculture, education, health and the food industry/catering.

5) Consideration should be given to those who sell disinfectants at the local retail level e.g. supermarkets and other shops/outlets. Through the retailers associations, mangers of such shops should be aware of the differentiation between professional users and the general public. A stronger onus should be placed on ensuring they are supplying the SDSs to those persons who are using the products in a professional capacity.

6) Where younger persons are embarking on apprentice schemes, training programs, city and guilds, various vocational courses etc those skills/work/trades which involve the need to use disinfectants could be identified so as to ensure the training provided includes this issue/element within the training schedule.

7) In some of the workplaces being examined above SDSs are available, but are in an office which is often times locked and empty at the time these professional users are working. Equally the SDSs may be stored in a file and are never taken out, read or distributed further than that office. Therefore some of the improvements required to address this concern relate to the need for behavioural changes also.