

A RISK MANAGEMENT OVERVIEW FOR DECIDING AND REVIEWING THE USE OF SPECIFIC SANITISER IN A SCHOOL SETTING (ISO 14971:2019)

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Summary:

With almost 1,000,000 students set to return to school in Ireland this September, this risk analysis was carried out to examine the safety, efficacy, benefits and drawbacks of each biocidal product registered for use by the Department for Agriculture. Sanitiser products contain ingredients that can cause side-effects that range from minor irritations to serious adverse events and death. For this reason, we have carried out a detailed search on each product, with regards to the severity of side-effects, the likelihood taking different age groups into consideration and the actions required to minimise risk of the students, staff and the wider community. This document has been designed with reference to protocols issued by the Department of Education - see attached link for full review.

<https://www.education.ie/en/covid-19/interim-recommendations-for-the-reopening-of-schools-and-educational-facilities.pdf>

The objective of this risk analysis is to ensure that principals throughout the country make an informed choice concerning the sanitiser product and sanitiser station that will be made available to the students in each respective school.

A. Selection of Sanitiser Product

| Function | Potential Risk | Risk Reduction - Control Measure | Action Required |
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| 1.Efficacy | | | |
| Alcohol sanitiser | Needs primary EN 1500 testing and if possible, Sarsi Cove -2 kill study | Check documentation and if not available should be in accordance with WHO Recommendations. | Ensure only validated / regulated products used according to the Biocidal Products Register and the World Health Organisation. |
| Non - Alcohol sanitiser | Needs primary EN 1500 testing and if possible, Sars Cov -2 kill study | Check documentation - all products should have primary data of efficacy studies with reference to Coronavirus and more specifically Sars Cov-2 kill studies. | Ensure only validated products used with appropriate documentation that is in line with the Biocidal Products Register. The World Health Organisation website offers information on the use of these products and their possible side-effects. |
| 2.Safety | | | |
| 2.1 Side-effects upon intentional/accidental ingestion: | | | |
| Function | Potential Risk | Risk Reduction - Control Measure | Action Required |
| Alcohol sanitiser (< 10 years) | High risk – High probability | Used with 100% supervision | Only used under supervision, no direct access to pupils. Ensure alcohol products are kept out of reach of children until sanitization is required. |
| Alcohol sanitiser (>10 years) | High risk – High probability (Intended ingestion & abuse) | Used under caution | Used with Caution and in supervised areas only, no direct access without supervision. Educate students on the dangers of concentrated alcohol according to the WHO. https://www.who.int/gpsc/tools/faqs/abhr2/en/ See Safety Data Sheet for each respective alcohol containing product. |
| Non - Alcohol sanitiser | Risk analysis of active ingredients to be determined by ingredients and toxicology profile accessed by product. | | Depends on active ingredients - see below. |
| | Low risk - Low probability (all ages) | 1. Hypochlorous acid | Low Risk – No action needed. Suitable for all age groups. GRAS - (Generally regarded as safe upon ingestion). https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk – High probability (<10 years) low probability (>10 years) | 2. *Conventional Chlorine compounds -Hypochlorites (ClO-) (e.g., Sodium hypochlorite • Chlorine dioxide (ClO2) • Chloramine-t trihydrate (C7H7ClNNaO2S) | Medium Risk - Use under supervision. See Safety Data Sheet for each respective chlorine containing product. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |

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| Medium risk – High probability (<10 years) Low probability (>10 years) | 3. Povidone-iodine (polyvinylpyrrolidone with iodine) | Medium risk – Use under supervision. Ingestion can cause stomach upset, vomiting, diarrhoea, and burning of the gastrointestinal tract. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| Medium risk – High probability (<10 years) Low probability (>10 years) | 4. ** Quaternary ammonium compounds - Benzalkonium chlorides, including alkyl dimethyl benzyl ammonium chloride, • Benzyl dimethyl octyl ammonium chloride, • Didecyl dimethyl ammonium chloride | Medium Risk depending on active ingredient. Refer to product Safety Data Sheet for specific compound as there are number of actives in this category. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| Medium risk – High probability (<10 years) Low probability (<10 years) | 5. Hydrogen peroxide (H2O2) • Peracetic acid (PAA) (C2H4O3) | Medium risk, should not be used on young children < 2 years - Use under supervision. Can cause systemic toxicity, gastrointestinal irritation diarrhoea and vomiting. Refer to product Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| Medium risk – High probability (<10 years) Low probability (>10 years) | 6. Triclosan Penetrate | Mild to medium risk - Use under supervision. The FDA banned the chemical's use in antibacterial liquid soaps in 2016. https://www.fda.gov/news-events/press-announcements/fda-issues-final-rule-safety-and-effectiveness-antibacterial-soaps |

2.2 Dermal side-effects upon skin exposure:

| Function | Potential Risk | Risk Reduction - Control Measure | Action Required |
|--|--|--|---|
| Alcohol sanitiser (< 10 years) | High risk – High probability (<10 years) | Used with 100% supervision | Only used under supervision, no direct access to pupils < 10 years Medical history of student should be sought to ensure no skin conditions such as psoriasis or eczema. Should not be used on cuts, grazes or skin conditions. |
| Alcohol sanitiser (>10 years) | High risk - High probability (>10 years) | Risk analysis of individual student to determine history of skin conditions. | https://www.irishdermatologists.ie/about-us/updated-frequent-hand-washing-advice |
| Non - Alcohol sanitiser | Risk analysis of active ingredients to be determined by ingredients and toxicology profile accessed by product. | | Depends on active ingredients - see below. https://www.irishdermatologists.ie/about-us/updated-frequent-hand-washing-advice |
| | Low risk | 1. Hypochlorous acid products 160ppm -260ppm | Low Risk – No action needed. Suitable for all age's groups irrespective of skin conditions. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk | 2. Conventional Chlorine compounds – * as above | Medium - Use under supervision. Can cause irritation and burning to skin, nose, eyes and throat. Use with caution. https://www.irishdermatologists.ie/about-us/updated-frequent-hand-washing-advice |
| | Medium risk | 3. Povidone-iodine (polyvinylpyrrolidone with iodine) | Medium risk – Use under supervision. Side effects on dermal tissue includes welling irritation, itching and rash. Iodine is corrosive to the skin. https://escholarship.org/uc/item/14h5d8wg |
| | Medium risk | 4. Quaternary ammonium compounds - * * as above | Medium Risk – Use under supervision. Contraindicated in children with skin conditions. Associated with allergies /dermatitis. Student medical history should be sought to ensure child has no history of allergic skin conditions. https://pubmed.ncbi.nlm.nih.gov/5009625/ |
| | Medium risk | 5. Hydrogen peroxide (H2O2) • Peracetic acid (PAA) (C2H4O3) | Medium risk, should not be used on young children < 2 years Risk of dermal irritation and other systems should the product be absorbed through the skin. https://www.healthline.com/health/hydrogen-peroxide-skin#1 |
| | Medium risk | 6. Triclosan Penetrate | Mild to medium risk associated with dermatitis – medical history should be sought to ensure child has no history of allergic skin conditions. Use under supervision. https://www.fda.gov/news-events/press-announcements/fda-issues-final-rule-safety-and-effectiveness-antibacterial-soaps |

| 2.3 Ocular side-effects upon exposure: | | | |
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| Function | Potential Risk | Risk Reduction - Control Measure | Action Required |
| Alcohol sanitiser (< 10 years) | High risk - High probability (<10 years) | Used with 100% supervision. | Only used under supervision, no direct access to pupils. Parents medical history of student should be sought to ensure no eye conditions. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| Alcohol sanitiser (>10 years) | High probability (>10 years) | Used under caution. | |
| Non - Alcohol sanitiser | Risk analysis of active ingredients to be determined by ingredients and toxicology profile accessed by product. | | Depends on active ingredients - see below. |
| | Low risk - Low probability (<10 years) Medium probability (>10 years) | 1. Hypochlorous acid | Low Risk – No action needed. Suitable for all age's groups irrespective of skin or eye conditions. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk – High probability (<10 years) Low probability (>10 years) | 2. Conventional Chlorine compounds - * as above | Medium - Use under supervision. Risk of ocular irritation and burning. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk – High probability (<10 years) Low probability (>10 years) | 3. Povidone-iodine (polyvinylpyrrolidone with iodine) | Medium risk – Use with caution. Iodine compounds can cause serious ocular burns. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk - High probability (<10 years) Low probability (>10 years) | 4. Quaternary ammonium compounds - ** as above | Medium Risk – Use with caution. Can cause ocular burning and stinging. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk – High probability (<10 years) Low probability (>10 years) | 5. Hydrogen peroxide (H2O2) • Peracetic acid (PAA) (C2H4O3) | Medium risk - Should not be used on young children < 2 years. Use with caution. Risk of eye irritation but serious injury is very rare. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | Medium risk – High probability (<10 years) Low probability (>10 years) | 6. Triclosan Penetrate | Mild to medium risk – Use with caution. Can cause minor eye irritations. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| 2.4 Side-effects upon accidental sanitiser inhalation: | | | |
| Function | Potential Risk | Risk Reduction - Control Measure | Action Required |
| Alcohol sanitiser (< 10 years) | High risk – High probability (<10 years) | Used with 100% supervision. | Only used under supervision - Used with caution. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| Alcohol sanitiser (>10 years) | High probability (>10 years) | Used under caution. | |
| Non - Alcohol sanitiser | Risk analysis of active ingredients to be determined by ingredients and toxicology profile accessed by product. | | Depends on active ingredients - see below. |
| | Low risk - High probability (<10 years) Medium probability (>10 years) | 1. Hypochlorous acid activity 150 ppm to 280ppm | Low risk – No action needed. Hypochlorous acid should not be inhaled however low risk at concentration below <260ppm. See Safety Data Sheet and check each product for concentration of the active ingredient. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |
| | High risk – High probability (<10 years) Low probability (>10 years) | 2. Conventional Chlorine compounds - * as above | Medium risk – Use with caution. Chlorine compounds can cause respiratory distress, airway constriction and fluid accumulation. See Safety Data Sheet. https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name |

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| High risk - High probability (<10 years) Low probability (>10 years) | 3. Povidone-iodine (polyvinylpyrrolidone with iodine) | High risk – Use only under supervision. Iodine vapor is intensely irritating to mucous membranes and adversely affects the upper and lower respiratory system. See Safety Data Sheet. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name) |
| High risk - High probability (<10 years) Low probability (>10 years) | 4. Quaternary ammonium compounds - * * as above | Medium risk – Use with caution. Can cause bronchoconstriction and lung damage. See Safety Data Sheet. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name) |
| High risk - High probability (<10 years) Low probability (>10 years) | 5. Hydrogen peroxide • Peracetic acid (PAA) | Medium risk – Use with caution. Can be toxic if inhaled and causes respiratory irritation. See Safety Data Sheet. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name) |
| High risk – High probability (<10 years) Low probability (>10 years) | 6. Triclosan Penetrate | Medium risk – Use with caution. Can be toxic if inhaled and causes respiratory irritation. See Safety Data Sheet. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name) |

B. Selection/Discussion of Sanitiser Station with regards to Dispensation of Sanitiser and Social Distancing

| Function | Potential Risk | Risk Reduction - Control Measure | Action Required |
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| Fixed point sanitisation dispensers with regard to social distancing guidelines – No touch needed for dispensing of sanitiser | High risk of cross contamination during sanitisation process in standard classroom setting if station set at the point of entrance leading to an increase in transmission possibilities. | Decrease sanitisation to small pod of students - or individual labelled sanitisation. If sanitisation is to occur in groups, organise strict timetables to reduce cross-transmission between students. Sign-in sheets should be incorporated to ensure group numbers remain low and reduce the risk of transmission. Should there be an outbreak of the coronavirus, this may also assist with traceability. | Decrease class size – not practical in all settings. Essentially, the closer the school can get to personal sanitisation the lower the risk of transmission. Rating of best practice: 1. Personnel sanitisation 2. Pod sanitisation between small numbers of students 3. Mobile sanitisers to facilitate student flows ensuring ergonomics of school 4. Access & egress sanitisation points (https://www2.hse.ie/conditions/coronavirus/protect-yourself-and-others.html (Centre for Disease Control and Prevention) (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html) Note: Increase sanitisation points leads to increase in social distancing leading to decreased transmission rates. Ensure sign-in sheets are present to record numbers of students sanitising at different time intervals. The sign-in sheets also assist with traceability in the case of an outbreak of coronavirus within a school community. |
| Surface infected fomites during lunch or work-stations | High risk - Use a product that has PT 1, PT 2 and PT 4 approvals and is safe upon contact with food. | Encourage the disinfection of surfaces before returning to desks and before and after consuming food at lunch times. | Use aerosol-based dispensers to clean area at lunch times, needs to be PT4 approved and safe if used on food. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Per product name) |
| Accidental use on open skin or child population working with dry skin conditions | High risk | Cuts scrapes and skin cracking is normal in all general population of children – not practical to do a risk analysis per child. Alcohol-based sanitisers are not suitable as pH will cause stinging sensation and will lead to non-compliance and usage for child groups. | Use a sanitiser that is safe and does not sting upon use on macerated tissues. Example: Hypochlorous acid Alcohol-based hand products are very dehydrating to the skin and should only be used with caution in children with atypical skin conditions. This is ameliorated by dry skin conditions such as eczema or psoriasis/dermatitis – hypersensitivity reaction to active ingredients and chemicals used in certain sanitisers. (https://www.irishdermatologists.ie/about-us/updated-frequent-hand-washing-advice) |
| Flammable storage | High risk with alcohol - based products. Store out of sunlight and prevent access to children. | Store sanitiser away from electronics and batteries. Store in an open space where use can be supervised. | Review Safety Data Sheet for advice and cautions. In general alcohol-based products are flammable and should not be used or stored anywhere close to sparks or naked flames. Check flammability of other sanitiser products on the product Safety Data Sheet. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/ Pr product name) |

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| <p>New data out on aerosol particles</p> | <p>High Risk</p> | <p>Fogging may be currently the best solution, however there is a shortage of approved solutions for fogging. In the absence of this, a sanitiser with an aerosol dispenser is best practice allowing application of sanitizer product onto skin with superior coverage. Fogging also results in the killing of all microorganisms contained in the airspace through which the aerosol travels. Alcohol-based products would be unsuitable due to possibility of getting into mucous membranes and eyes.</p> | <p>Use a water-based sanitiser with aerosol dispenser. The Biocidal Products Register should be checked for the approved use of products as fogging devices. (https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/) See individual Safety Data Sheets</p> |
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Conclusion:

Coronaviruses are a family of enveloped, single-stranded, positive-strand RNA viruses classified within the Nidovirales order. This coronavirus family consists of pathogens of many animal species and of humans, including the recently isolated severe acute respiratory syndrome coronavirus (SARS-CoV). Based on the efficacy, safety, risk and probability of occurrence associated with each sanitiser product, we can conclude there are varying safety profiles for each respective sanitiser. All categories listed in the risk analysis are approved with Biocidal Products Register (<https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/>) and evidence on killing capacity for coronavirus should be reviewed on a case by case basis. As all listed products effectively sanitise, it is the responsibility of school management to draw their own conclusions on the safest product for use in their own school environment. When doing this, they must consider the age of their student populations along with side-effects associated with ingestion, contact with the skin, eyes and inhalation.

For certain students, patient medical history review may be necessary. For example, a child with severe dermatitis may experience a hypersensitivity reaction upon dermal contact with concentrated alcohol sanitizer. While it is not practical to individualise sanitizer treatment for each student, Principals should be aware of extreme cases and make accommodations for these students, while maintaining standard social distancing practises and guidelines as detailed above.

Alcohol-based sanitizers are certainly an option, particularly for non-routine or incidental use in accordance with the WHO guidelines. However, if we are to stop the spread of the virus the alcohol-based products are clearly not the most child-friendly option. As discussed above they are in the high-risk category for ingestion and can cause considerable dermal and ocular irritation. The safety profile along with a pungent unpleasant odour could lead to non-compliance in child age groups and compliance with these guidelines is vital if the spread of the virus is to be prevented. These products would require supervision and student history while being used and this would not be easy to employee in a dynamic school setting. Alternatively, non - alcohol products appear to be less harsh on the skin during prolonged use. A product pH in the range of 5 – 7 will result in no sting upon application. These products are more child-friendly and would not demand the same level of supervision. Based on the safety profile of each sanitisation compound, non-alcohol sanitisers appear to be superior in terms of a safety profile for child use and should result in greater compliance however their efficacy on killing Sar-Cov-2 should be individually accessed.

In conclusion, the deciding factor on balance will be the final risk benefit analysis of the specific product in killing the pathogen while causing least possible harm.

Hypochlorous acid products (non-alcohol) appear to pose the lowest risk in terms of ingestion, inhalation, dermal and ocular contact with proven efficacy.

References:

1. COVID-19 Interim Recommendations for the reopening of schools and educational facilities
<https://www.education.ie/en/covid-19/interim-recommendations-for-the-reopening-of-schools-and-educational-facilities.pdf>
2. Biocidal Products Register – Department for Agriculture Food and the Marine
<https://www.pcs.agriculture.gov.ie/registers/biocidalproductregisters/>
3. World Health Organisation – Rolling Updates on Coronavirus Disease (Covid-19)
<https://www.who.int/gpsc/tools/faqs/abhr2/en/>
4. Centre for Disease Control and Prevention
<https://www.cdc.gov/coronavirus/2019-nCoV/index.html>
5. US Food and Drug Administration
<https://www.fda.gov/news-events/press-announcements/fda-issues-final-rule-safety-and-effectiveness-antibacterial-soaps>
6. Irish Association of Dermatologists
<https://www.irishdermatologists.ie/about-us/updated-frequent-hand-washing-advice>
7. HSE – Controlling Exposures to Disinfectants
https://www.hsa.ie/eng/topics/biological_agents/biological_agents_introduction/disinfectants/
8. The college of Optometrists
<https://www.college-optometrists.org/the-college/media-hub/news-listing/coronavirus-2019-advice-for-optometrists.html>
9. Dermatology Online Journal
<https://escholarship.org/uc/item/14h5d8wg>
10. PubMed
<https://pubmed.ncbi.nlm.nih.gov/5009625/>