TOXICOLOGICAL SAFETY ASSESSMENT

Nanochlor - Nanopure
Effervescent Disinfectant AgNP with HOCL Tablet

Customer Reference: NACH006

CONFIDENTIAL

DELIVERED TO:

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DATE:

June 29, 2022
Report ID: LEIC-NSA-TRAG-2
Intertek ID: 26386

Toxicological Safety Assessment

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Customer Reference: NACH006

Product Information

The assessed product is an effervescent tablet used as a disinfectant for pre-cleaned surfaces. It is recommended that the dissolved tablet in tap water and the solution can be sprayed on the surface intended to be disinfected.

Formulation

See Appendix One for product formulation data

Assessment Conclusion

From a toxicological perspective, the formulation is considered suitable for use as a surface disinfectant for the South African market. Suitable personal protective equipment (PPE) should be worn during use including any pre-mixing/dilution in accordance with the information laid out in the Safety Data Sheet and instructions of use for this product. The labelling including H and P phrases should also be consistent with the GHS compliant Safety Data Sheet. The surface should be thoroughly rinsed in accordance with good cleaning practices.

Potential contamination from residual amounts of this product and any kind of secondary exposure has not been risked assessed in this report.

This statement only applies to the product with the formula identified above. Any change in the formula, including any quality aspect, requires a new, up-dated safety assessment for the formula affected.

After a review of all available information including formulation, exposure to the product and the toxicological profile of the ingredients, it is concluded that, according to the current state of scientific knowledge, this product is considered suitable for its intended use as a hard surface disinfectant.
The toxicological data available on the individual substances and the end product, including human exposure via intended and likely routes have been taken into account in this assessment. Where applicable, relevant systemic and local toxicity end points of the chemicals ingredients in this formulation have been considered as part of this risk assessment.

Labelling Warnings and instructions for use

Warnings

For professional use only
Do not breathe mist/spray.
Avoid contact with skin and eyes.
Wear appropriate personal protective equipment especially when handling.
Wash hands thoroughly after handling.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue Rinsing

Additionally, the product should be labelled in accordance with GHS labelling rules and consistent with the SDS.

Instructions of Use

Follow the directions of use as given on the packaging label and the precautions included in the safety data sheet.

Fragrance Allergen Labelling

NA

Reasoning

Product Toxicity Review

Substances are present in this formulation which are classified as Hazardous to Health in accordance with Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the formulation is classified as Hazardous. If used as directed in a professional environment under controlled conditions, the use of this product should be uneventful.

Effects of the product as provided on the skin

The formulation as supplied may cause severe skin irritation.
Repeated exposure to the formulation as supplied is unlikely to produce allergy by skin contact.
Contact with the dilute solution is unlikely to cause skin irritation even if contact is prolonged and/or repeated.

Effects of the product as provided on the eye

Corrosive to Eyes.
Accidental exposure of the eye to the diluted product may result in slight eye irritation.

Effects following ingestion of the product as provided

Ingestion is an unlikely route of exposure.
The formulation as supplied if swallowed would cause severe irritation of the mouth and upper digestive tract and cause damage to internal organs.
The diluted product if swallowed may cause slight, transient irritation to the mouth and upper digestive tract.

Effects following inhaling of the product as provided

Prolonged inhalation of high concentrations of the spray and aerosol may cause respiratory irritation and damage to the internal organs.

Ingredient Toxicity Review

The assessed effervescent tablet is used as a general-purpose disinfectant. The substances present in the formula are commonly used and do not pose a particular hazard to the professionals as detailed below, particularly when used as directed.

Sodium dichloroisocyanurate, the active biocide, liberates hypochlorous acid in water and is known to be used in applications which include sterilizing drinking water, baby bottle, and swimming pools. The primary mode of action of active chlorine released from sodium dichloroisocyanurate in aqueous solutions is characterised by local irritation/corrosion and oxidation at the site of the first contact triggered by direct chemical reactivity. All chlorine products have some level of toxicity. Upon ingestion of chlorinated water, the available chlorine is rapidly reduced by saliva and stomach fluid to harmless chloride salts (Kotiaho, T., Wood, J.M., Wick, P.C., Dejarme, L.E., Ranasinge, A., Cooks, R.G., 1992. Time persistence of monochloramine in human saliva and stomach fluids. Environ. Sci. Technol. 26, 302–306.).

As reported "Regarding chlorinated isocyanurates, studies identified these no more than slightly toxic and not corrosive. Chronic and sub-chronic toxicity studies also found no toxicity. Chlorinated isocyanurates are not metabolized in the body and do not bioaccumulate. JECFA has recommended that the tolerable daily intake (TDI) for anhydrous NaDCC from treated drinking water be set at 0–2.0 mg per kg of body weight per day (WHO, 2004). Using standard methods (WHO, 1993) guideline values (GVs) for NaDCC can be derived from the TDI. This translates into a GV for adults (60 kg, with a daily drinking water consumption of 2 l) of 60 mg/l NaDCC; a GV for children (10 kg, with daily consumption of 1 l) of 20 mg/l NaDCC; and a GV for infants (5 kg, with daily consumption of 0.75 l) of 13 mg/l. The dosage rate for Aquatabs, for example, is between 3.5 and 7 mg/l NaDCC (2–4 mg/l FAC), well within the JECFA value for daily intake (TDI)." (reference: T. Clasen, P. Edmondson / Int. J. Hyg. Environ.-Health 209 (2006) 173–181). Moreover, Sodium dichloroisocyanurate is being evaluated for use as a biocidal active ingredient under Biocidal Products Regulation ((EU) No 528/2012 (BPR)) in PT02 - Disinfectants and algaecides not intended for direct application to humans or animals and PT04: Food and Feed area. The main toxicological concern associated with this ingredient is oral acute toxicity, severe eye irritation and respiratory irritation. It has harmonised classification under Annex VI of CLP Regulation (EC) No 1272/2008 as Acute Tox. 4, Eye Irrit. 2 and may cause respiratory irritation at a concentration ≥10%.

Silver and nanosilver are clearly shown to have toxic potential although toxicity in general in humans seems to be low. In in-vitro studies, Ag-NPs (Nanoparticles) are cytotoxic and have genotoxic DNA damaging capacity and show developmental toxicity. In-vivo genotoxicity and developmental toxicity studies could not confirm or negate the effects of Ag-NP. Although Ag uptake and possible persistence in the testes was observed, histopathology did not reveal specific testicular toxicity. Liver toxicity is indicated by the effect of Ag-NPs on various liver enzymes. In vivo, effects on the immune system were observed both regarding an allergy to Ag itself, but also in repeated dose toxicity studies regarding effects on cytokine production and on non-specific immune responses like natural killer cell activity. These immune effects warrant further studies exploring the functionality of the immune system after exposure to Ag-NPs. Bioavailability of silver after oral administration of Ag-NPs in rats was shown and in one study it was suggested to be in the range of 1-4 % of the oral dose. This study provides preliminary evidence of low dermal absorption. Considering the nature of the use of this product, dermal and inhalation routes are considered to be most relevant. Moreover, in absence of specific conclusive hazard information, it is recommended that adequate PPEs are worn to limit the exposure during product application. In the present risk assessment, NIOSH-derived recommended exposure limit (REL) for silver nanoparticles (<100 nm primary particle size) of 0.9 µg/m3 as an airborne respirable 8-hour time-

weighted average concentration has been considered as the worst-case AEC acute/medium-term/long-term for professional workers. This AEC is expected to be protective of the lung and liver effects (bile-duct hyperplasia) observed in sub-chronic inhalation studies in rats.

The concentration of Nanosilver in the product is at 0.016%. As per client information, this product is to be used after dilution (1x 6g tablet makes a 2000ppm solution)and sprayed on the surface intended to be disinfected. The minium dilution level of 500 mL has been considered for risk assessment as it will cover the more diluted exposure scenarios. When integrated with the inhalation exposure as recommended by TNsG June 2002 (PT2, PT 4 Professional hard surfaces disinfection Surface disinfection model 1), diluted concentration in the product of 0.000032%, leads to potential inhalation exposure of 0.000032 µg/m3 of AgNP. The risk characterization with the NIOSH-derived recommended exposure limit (REL) of 0.9 µg/m3 for AgNP, demonstrates that the exposure levels are much lower. Further, the wearing of PPEs such as hand gloves would minimize the dermal exposure during mixing, handling and application. Hence, no safety concerns are expected when used as per directions of use provided by the client. **The safety evaluation for high-pressure spray applications including fogging that could lead to the generation of fine mist or aerosol particles has not been considered in this risk assessment.**

Due to the inherent properties of ingredients and their concentrations in this product, the neat product would be classified as corrosive to skin and eyes. The following precautionary warnings are required to protect the user:

For professional use only
Do not breathe mist/spray.
Avoid contact with skin and eyes.
Wear appropriate personal protective equipment especially when handling.
Wash hands thoroughly after handling.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue Rinsing

A safety data sheet should be provided to the user and this should include full hazard and labelling elements which are not given as part of this toxicological risk assessment. It must be ensured that adequate personal protective equipment's are used during the handling and application of the product.

Overall, the use of this product for misting and fogging is not recommended however, the surface application is not expected to be of concern when used in accordance with good cleaning practice.

Margin of Safety Review

Not applicable. The risk of local effects of irritation is negligible with the use of recommended PPE by the professional during the handling and application of the product.

See Appendix One for a toxicological review of the formulation ingredients

Exposure Scenario

As a professional only use product, it is expected that exposure would be minimized by the operator wearing personal protective equipment such as gloves, safety goggles, respiratory mask, and protective clothing.

Product Class: Biocidal product

Product Group: General Products

Part of body exposed to undiluted: No contact with the skin during normal use

Product Name: Nanochlor - Nanopure Effervescent Disinfectant AgNP with HOCL Tablet

Fragrance Composition

This formulation does not contain a synthetic fragrance and therefore a fragrance safety evaluation as per the IFRA code of practice is not applicable to this product.

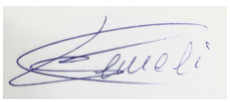
Assessor's Credentials and Approval

This product was evaluated by S. TALREJA who is qualified by education, training and experience to evaluate the safety of this product formulation.

S. TALREJA,M.S. Pharm (Pharmacology & Toxicology), MRSB, EUROTOX Registered Toxicologist
Intertek Assuris

Date: June 29, 2022

This product was reviewed by E. CEMELI who is qualified by education, training and experience to evaluate the safety of this product formulation.



E. CEMELI, BSc, PhD (Toxicology)
Intertek Assuris

Date: June 29, 2022

Appendix One: Product Formulation Data and Toxicological Review of Ingredients

Formulation

The chemical names shown below refer to the raw materials used to formulate this product. The identity of the raw materials may be based on alternative nomenclature such as IUPAC name, Chemical name, INCI name or generic trade name. Furthermore, there may be instances where several CAS number exist for the same chemical ingredient. Where this has occurred, the most appropriate substitute will have been used where one has not been provided.

Chemical Name	% Concentration	% Active	Activity in Product	CAS No	INCI Name
SODIUM DICHLOROISOCYANURATE ANHYDROUS, SODIUM DICHLOROISOCYANURATE DIHYDRATE	51	100	51	2893-78-9, 51580-86-0	
NANO SILVER (AGNP)	0.016	100	0.016	7440-22-4	SILVER

Margin of Safety Calculation

INCI Name	Conc. (% w/w)	SED mg/kg	NOAEL/NOEL mg/kg bw/day	MoS
SODIUM DICHLOROISOCYANURATE ANHYDROUS, SODIUM DICHLOROISOCYANURATE DIHYDRATE	51			
NANO SILVER (AGNP)	0.016			

END OF REPORT