EN 1276:2019

TOXICOLOGY SAFETY ASSESSMENT
LIQUID SANITISER 80% (FOR HANDS & SURFACES)

PRODUCT INFORMATION	Biodelta Liquid Sanitiser 80% (for hands & surfaces)
Batch Number	BIO 001 DM
Batch Size	5000 L
Expiry Date	06/04/2021
Lab Ref No#	LEIC-BIO-TRAG1 23803
Laboratory	Intertek Leicester Centre, Meridian Business Park, Leicester, Great Britain, LE19 1WD

EXPOSURE SCENARIO

Targeted Population	Adults
Body Weight (kg)	60
Skin Surface Area cm²	840
Part of Body Exposed	Hands
Applications per day	25
Amount apply per day (g)	20
Exposure Time (minutes)	240
Retention Factor	1
% Weight fraction transfer to skin	100

FORMULATION DATA

CHEMICAL NAME	CAS NO	INCI NAME	% CONC
Alcohol Denat (Ethanol Denat)	64-17-5	ALCOHOL DENAT	83,33
Glycerin; Glycerol	56-81-5	GLYCERIN	N/A
Hydrogen Peroxide	7722-84-1	HYDROGEN PEROXIDE	N/A
Aqua (Water)	7732-18-5	AQUA	N/A

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, use of this product formulation should be uneventful in the majority of the target population.

ASSESSMENT CONCLUSION

From a toxicological perspective, the formulation is considered suitable for use as a hand/surface sanitizer. The labelling including H and P phrases should also be consistent with the GHS compliant Safety Data Sheet. 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.
Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give the target population the level of safety they can reasonably expect when used as directed.
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.

Assessor's Credentials and Approval
This product was evaluated by the following people who is qualified by education, training and experience to evaluate the safety of this product formulation.

Intertek Health, Environmental & Regulatory Services (HERS):
D. SANCHEZ CARVAJAL,BSc (Veterinary), MSc (Toxicology)
O. AKINTOYE, BSc, MSc (Toxicology), MSB, PgDip. Occ. Hyg.,
EUROTOX Registered Toxicologist

INGREDIENT TOXICITY REVIEW

Liquid hand and surface disinfectant composed primarily of alcohol and water. The product is expected to be applied onto hands or surfaces and rubbed in/left to dry. Thus, dermal contact is the predominant route of exposure.
Inhalation of evaporated alcohol is expected albeit minimal due to dilution in air and air exchange via ventilation. Oral ingestion is not expected under normal and reasonably foreseeable conditions of use. In a HSE UK - A review of the data on efficacy of hand cleaning products in industrial use as alternatives to handwashing (2014), the following conclusion was reached: '*the 'dose' of alcohol based product used per application is critical to the success of its use.*
Studies show that at least 3 ml of product should be applied to the hand. More than 4 ml is not likely to improve efficacy providing that at least 3 ml is normally applied. This should equate to sufficient alcohol based product to fully lubricate both hands, so that a film of liquid product can be felt to cover the skin of the hands'.
The main ingredient is the biocidal active, ethanol, which is included in the EU Biocidal Review programmes for use in human hygiene and also food and feed area disinfectant. It is a well used ingredient in these product types and included in WHO standard formulations for hand sanitizers. There is clear evidence that ethanol is an eye irritant. It is however, not sensitising or irritating to skin. Also, noteworthy that there is some evidence from human volunteer studies that repeated application under extreme occlusive conditions can lead to chronic irritation. Therefore, individuals with particular sensitivity or susceptibility to ethanol may be more prone to irritation when using the product. It may also cause some stinging when applied to damaged skin. The pertinent toxicological risk with the alcohol is central nervous system (CNS) depression including drowsiness and dizziness if inhaled at the very high concentration in the formulation although very unlikely. For the application as a hand sanitizer, it would be via a dispenser and inhalation of evaporated alcohol is expected to be minimal thus posing negligible risk of CNS effects.

The application as surface sanitizer may cause substantial concentration in the surrounding air if not use in well ventilated area and this could pose a risk. However, it is noteworthy that intoxication effect is rarely reported for inhalation exposure to ethanol at up to the occupational exposure limit of 1900 mg/m3. The product label should include the warning to use in well ventilated.
Glycerin and Hydrogen Peroxide pose no significant toxicological risk either local or systemic as formulated in the product.

Overall, there is low to negligible risk of systemic toxicity effects with the application of the product as leave on hand disinfectant. Nonetheless, prolonged, repeated application may cause skin dryness/cracking which could predispose individuals to cutaneous irritant reaction. Hence, it is recommended to include on the label the warning to 'discontinue use if rash or irritation occurs' and 'do not use on broken or damaged skin'.

Pharmaceutical Director
NM Swart (B.Pharm)

CERTIFIED FOOD SAFETY MANAGEMENT SYSTEM ISO 22000