Biocompatibility Report
HospiCare Adult Body Wipes 40R

1. Introduction

In the selection and approval of materials for medical devices, it is essential to consider more than just physical properties and cost-effectiveness. Materials may contain components that pose potential biological risks, including toxicity. Therefore, a comprehensive screening of candidate materials, along with a detailed evaluation of the final finished product under actual use conditions, is crucial. This biocompatibility report has been prepared in accordance with ISO 10993-1: *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*. As biological safety evaluation is an integral component of medical device risk management, the report also adheres to ISO 14971: *Application of Risk Management to Medical Devices*. The biological evaluation of Hospicare Adult Body Wipes 40R was conducted in alignment with the following standards: ISO 10993-1 for evaluation and testing within a risk management process, ISO 14971 for risk management, ISO 10993-5 for in vitro cytotoxicity testing, and ISO 10993-10 for irritation and skin sensitization testing.

2. Purpose

The purpose of the Biological Evaluation of HospiCare Adult Body Wipes 40R is to ensure, from a biological and toxicological perspective that, the device is safe to use.

3. Device Description

Device Name

HospiCare 40R Adult Body Wipes

Intended Use

Skin Cleansing wipe for external use

Categorization

According to ISO 10993-1 categorization, HospiCare Adult Body Wipes are considered a surface-contacting device with limited contact duration (up to 24 hours).

Materials

The HospiCare Adult Body Wipes are composed of non-woven fabric saturated with a formulated aqueous solution containing water, moisturizers, preservatives, fragrance, and

other skin-conditioning agents. Packaged in a resealable pouch for hygiene and product integrity.

4. Biological Evaluation Process

4.1. Material Characterization

Under the principles of ISO 14971, the first step in the biological risk assessment is the identification of material components and their potential hazards. The composition and functional role of each ingredient have been thoroughly reviewed.
The characteristics, major components, and operating requirements of HospiCare Adult Body Wipes that may affect the product's safety and intended use were identified.

Table 1: Major Components

INCI Name (Ingredients)	CAS No.	Function	Percentage %v/v	Substantial Equivalence	Risk Reference
Purified Water	7732-18-5	Base/ Diluent	98.350	Commonly used as a solvent in skin-contacting medical and cosmetic products; non-toxic.	Low
Phenoxyethanol	122-99-6	Preservativ	0.630	Widely used in topical formulation as a preser-vative; established safety profile in similar skin-contacting products	Low
Sodium Gluconate	527-07-1	Chelating agent	0.200	Common in cosmetics and skincare for stabilizing	Low

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				formulation; low toxicity and safe for dermal use	
Aloe barbadensis Leaf Juice	94349-62-9	Moisturizer Soothing Agent	0.200	Long history of safe use in skin-soothing products and cosmetics; generally recognized as safe for topical application	Low
Chlorphenesin	122-99-6	Preservativ	0.180	Used in personal care products for microbial control; considered safe at low concentrations for topical use	Low
Polysorbate 20	9005-64-5	Solubilizer	0.150	Non-ionic surfactant broadly used to solubilize ingredients in cosmetics; well tolerated by skin	Low
Chlorhexidine digluconate	18472-51-0	Antibacteri agent	0.100	Used in antiseptic wipes and topical disinfectants; safe for limited use in low concentrate-tions	Low
Fragrance	N/A	Fragrance	0.100	Fragrances are widely used in cosmetics;	Low

				potential allergenicity managed by low concentra-tion and limited exposure	
Glycerin	56-81-5	Solvent/ Humectant	0.090	Commonly used in medical and cosmetic skin formulation; has moisturizing properties and a long history of safe use	Low

All ingredients have established safety profiles and are commonly used in similar topical applications. Concentrations are maintained at levels well below those known to cause irritation or sensitization.

4.2. Risk Characterization

The chemical constituents of HospiCare Adult Body Wipes were assessed individually for potential toxicological risk. The materials used in the formulation have a well-established safety record in similar applications, and their low concentrations further minimize any potential for adverse effects. The table below summarizes the risk assessment of each major component:

Table 2: Risk Characterization Identification

Characteristics	Requirement/Specification
Chemical and Raw material used	Should minimize cytotoxicological harm to skin; ingredients selected based on history of safe use.
Preservative Composition	Should be safe according to cosmetic product standards; concentrations are within allowable limits.
Presence of foreign materials	Should be free from any form of foreign materials.

pH of the Finished Products	Formulated to be skin-compatible; no known adverse effects at the product's pH range.
Use and user error	Instructions must be clearly written and available to ensure correct application and avoid misuse.
Transport and storage	Product is stable under recommended conditions; packaging minimizes contamination risk during transport/storage.
Instructions on how the product is used	Must be available, clear and understandable
Stability Testing	Product must maintain its efficacy and safety throughout the shelf life
Packaging Characteristics	Packaging material should protect the product integrity
Microbial Contamination risk	Product should be microbial stable over its intended usage period.
Toxicological Testing	Skin irritation testing to confirm the product is safe for skin type
Expiration date	Product should have an expiration date to ensure its effectiveness within its intended period of use.

4.3. Microbial Risk Management

The HospiCare 40R Adult Body Wipes are designed to cleanse the skin. As such, microbial contamination during manufacturing, storage, and use could pose a risk to the user. The following microbial risk management considerations have been addressed:

Table 3: Microbial Risk Management

Risk Control Area	Potential Hazard	Potential Risk Consequence	Control Measure Description
Controlled Manufacturing Environment	Environmental microbial contamination	Microbial growth on wipes; infection or skin irritation during use	Product is manufactured in an ISO-certified facility under GMP, HACCP, and BCM controls. Production takes place in a Class 100K Clean Room to minimize contamination.
Use of Preservatives	Microbial growth post-manufacture	Contamination during storage/use; skin infection, reduced product efficacy	Phenoxyethanol, Chlorphenesin, and Chlorhexidine Digluconate are included as preservatives to inhibit

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			microbial growth over shelf life and usage.
Microbial Testing per Batch	Inadequate microbial quality prior to release	Distribution of contaminated product, potential adverse user reactions	Each batch undergoes TAMC and TYMC testing prior to release in accordance with internal QC procedure
Primary Packaging Integrity	Poor sealing/ Leaking	Post-opening contamination	Wipes are sealed in resealable packaging. QC Check for leaked during online production using leaked tester machine
Shelf Life and Stability	Degradation of preservative or microbial overgrowth	Reduced antimicrobial protection; user exposure to harmful microorganisms	Real-time and accelerated stability tests confirm preservative effectiveness and microbial control throughout shelf life
Biological Safety Evidence	Presence of microbial toxins or contamination	Skin irritation, allergic reaction, cytotoxicity	Testing under ISO 10993-5 and ISO 10993-10 confirmed non-cytotoxic and non-irritant characteristics, implying low contamination or toxic byproduct exposure.

This table demonstrates that risks related to microbial contamination are reduced as far as possible and remain within acceptable levels as per the ISO 14971 risk management process. Residual risks are addressed through appropriate labelling, storage instructions, and expiry dating.

4.4 Post-Market Surveillance

A review of the post-market history of similar products with comparable materials and use has not revealed any significant adverse events related to biocompatibility. This supports the conclusion that the HospiCare 40R Adult Body Wipes are unlikely to present an unacceptable risk to users.

Nonetheless, continued post-market surveillance is recommended as part of the manufacturer's vigilance and risk management strategy.

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4.5. Overview of Test Performed in Biological Evaluation and Test Result

The HospiCare 40R Adult Body Wipes, a surface-contacting device with limited contact duration (up to 24 hours), were evaluated for biocompatibility. The evaluation included cytotoxicity and skin irritation testing, as recommended by ISO 10993-1 for this type of device and contact duration. The following test reports were reviewed:

Test Type	Applicable ISO Standard	Purpose of Test	Contact Duration & Category	Result / Conclusion	Test Report Reference
Cytotoxicity	ISO 10993-5:2009	To assess if the product has any toxic effect on mammalian cells	Surface-contacting, ≤24 hrs (limited)	Non-cytotoxic	TÜV SÜD PSB Pte Ltd Report No. 7191043684-CHM12-LYP
Skin Irritation	ISO 10993-10:2010	To determine potential to cause irritation to the skin	Surface-contacting, ≤24 hrs (limited)	No evidence of skin irritation	TÜV SÜD PSB Pte Ltd Report No. 7191159425-CHM17-01-LY

The test results indicate that the HospiCare Adult Body Wipes are non-cytotoxic and do not cause skin irritation. Additionally, the product has undergone dermatologist testing, confirming its compatibility with human skin under normal conditions of use.

5. Conclusion

The biological evaluation shows that HospiCare Adult Body Wipes 40R is non-toxic a bd safe for its intended application. HospiCare Adult Body Wipes 40R, from a biological and toxicological perspective, is safe for user according to the intended application.

6. References

- *ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process*
- *ISO 14971 Medical Devices - Application of Risk Management to Medical Devices*

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- *ISO 10993-5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity*
- *ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization*

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