Baby Product Safety Report – Baby Lotion

I. Introduction

Parents want to provide the very best for their babies. Many would spend a lot of money to make sure that they have the safest products for their love ones. However, paying more for a product does not necessarily mean that they are safer. World Green Organisation (WGO), as a neutral party not affiliated with any brands within the baby product market, share the same concerns with parents and want to ensure that products that are used daily are safe for consumers. As such, WGO is setting a higher safety standard and creating a 'White List' of baby personal care products that have passed biological testing, chemical analysis, and international ingredient standards (this white list is dynamic and will grow and change as we test more baby personal care products). Consumers can use this list to facilitate purchase decision.

In order to ensure that the baby products are safe, WGO, in collaboration with three renowned laboratories, developed a 3-defense methodology, 1) biological testing and 2) chemical analysis, as well as 3) international ingredients standard checking, to test baby products found in Hong Kong. WGO decided to supplement chemical analysis with biological testing because the current government regulations only require chemical testing which checks if products contain any or too much chemicals that disturb key functions inside the human body. This does not take into account other factors such as chemical reactions that occur when ingredients are mixed together. In addition, due to the lengthy and expensive process, only a small percentage of chemicals' toxicity is fully known. According to the USEPA, there are still many unknown chemicals that are still being evaluated for potential human health effects[i]. Out of the 87,000 chemicals detected in 2006, "there is limited basic toxicity information for" of them. This is because there is no single entity and institution that measures the number of chemicals used commercially, let alone one that tests the toxicity of them.[ii]

In order to fully determine how chemicals in baby products affect the human body, effect-based biological methods must also be used. Through effect-based biological testing, we can cover a wider range of chemicals and determine whether the chemicals and the product are safe for human consumption. Products that are found to comply with biological criteria, chemical analysis, and international ingredient standards will be published in the 'White List' and deemed as safe products. To identify knowledge and awareness gaps within the general public, WGO also conducted face-to-face surveys in October and November 2016 with 200 Hong Kong parents with children under the age of 3. (For more details on the methodology of this study, please refer to the methodology section of this report.)

The objectives of this 3-year project are to:

- Raise public recognition to the potential health and safety threats through scientific product testing.
- Equip consumers with the information and knowledge needed to recognise safe products for their body and the environment.
- Encourage manufacturers, suppliers, and retailers to become more responsible and only produce products that meet biological, chemical, and international ingredient health standards by promoting public awareness and utilising consumer power.

Background

Baby Product Market Overview: The baby personal care products market has expanded exponentially in recent years. An article from Mintel reveals that products with the word 'baby' added has seen an 80% increase globally between 2008 and 2012[iii]. According to Accuray Research, the baby personal care product market is forecasted to increase another 18.2% in the next 10 years. This increased interest in baby personal care products means that there are a lot of products out there for consumers to choose from. However, every product is made differently and there are still some products available that may contain ingredients that are dangerous for humans to use.

It is important for consumers to look closely and carefully at the ingredients list of the baby personal care product we buy. Some chemicals can negatively affect hormones (a.k.a. Estrogenic Endocrine Disruptors) in the human body and have fatal health consequences such as development disorders, reproductive problems, respiratory issues, or even cancer, according to the World Health Organisation (WHO)[iv], Environmental Working Group (EWG)[v] and WebMD Feature[vi]. From our survey of 200 Hong Kong parents with children under the age of 3 conducted in October and November 2016, we found that only 22% of respondents always read the ingredient label. Over 60% answered that they were 'not sure' of the dangerous ingredients that they must look out. This finding shows that we need to educate the mass properly so that they know which products they can trust to use on their baby.

In addition to serious health consequences, these chemicals also harm the environment. When chemical substances and hormones are in the product, they are released into the environment after consumer use and disposal. The chemical components often degrade slowly and thus accumulate in the ecosystem. A build-up of some chemicals such as triclosan, dioxane, or DEA, can alter behaviour and cause death in many aquatic species as these chemicals also affect the hormones and genetics of animals[vii]. Chemicals that are introduced into aquatic ecosystems are transferred to other areas of life through rain. Every living organism are subsequently affected by these chemicals. This means that it is crucial and imperative for the personal care products that are used daily to contain no harmful and toxic ingredients that will have long-lasting effects.

I. Methodology

For this research project, we employed three methodologies: a) policy review; b) market review; and c) testing result analysis, including bio-testing, chemical testing, and international ingredient checking.

a) Policy Review

There are government regulations that are in place to ensure that products do not contain dangerous chemical substances. However, government regulations vary a lot depending on the country (see below for comparison) and usually only require the bare minimum.

Table 1. Different international government regulations

European Union[viii]	The 'EU Cosmetic Regulations 2016/1198', as of 22 July 2016, currently bans 1,300+ chemicals (this list doesn't limit to only cosmetic products) that are known or suspected to cause cancer, genetic mutation, reproductive harm or birth defects.
United States[ix]	As of 14 November 2016, the FDA only bans 11 chemicals. In addition, under the Federal Food, Drug, and Cosmetic Act, cosmetic products and ingredients do not need FDA approval before they go on the market. "Although U.S. regulations do not specify any particular testing

	regimens for cosmetic products or ingredients, it is the cosmetic company's responsibility to substantiate product and ingredient safety prior to marketing."[x]
China[xi]	The 'Safety and Technical Standard for Cosmetics', issued by China's Food and Drug Administration in 2015, will come into effect by 1 Dec 2016. The guideline will ban over 1,200 chemicals. Before companies can apply for a hygiene license or record-keeping certificate, companies have to make sure that their formula meets this standard.
Japan[xiixiii]	Japan's personal care products are regulated by the Ministry of Health, Labour, and Welfare under the Pharmaceutical Affairs Act. Japan's 'Standards for Cosmetics' came into effect April 2000 and is still used as of January 2015. It bans 16 chemicals from cosmetic products.
Hong Kong S.A.R.[xiv]	As of 2014, some products are regulated by 'Chapter 456 Consumer Goods Safety Ordinance', the 'Pharmacy and Poisons Ordinance', or the 'Chinese Medicine Ordinance'. Under these acts, the Hong Kong government will consider using international regulations (e.g. EU or FDA) as reference. But in general, there is no statutory regulation for skincare products in Hong Kong.

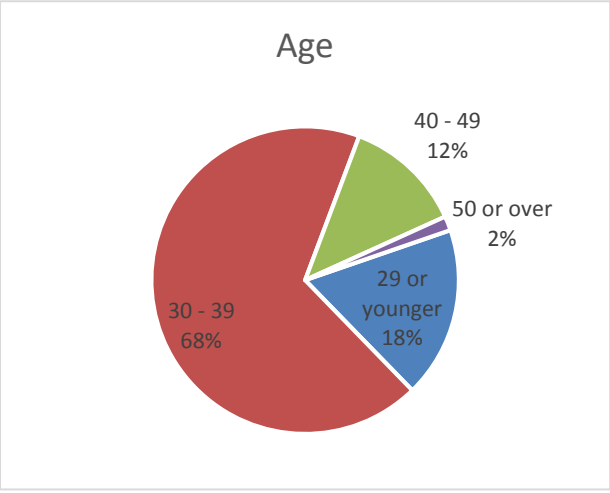
*Disclaimer/Note: All the regulations are up-to-date as the date of publication of the report.

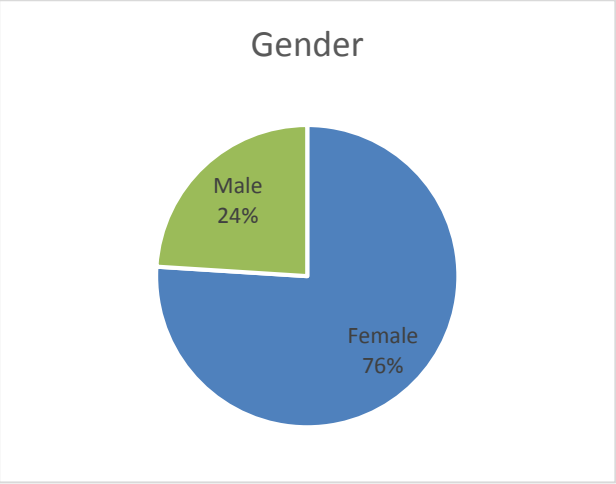
Since Hong Kong does not currently have a thorough assessment standard, WGO will also use international ingredient standards to ensure that these products sold in Hong Kong do not contain any banned ingredients.

The 'White List' will only contain products that have passed international ingredient standards, biological analysis, and chemical criteria. Through this process, we hope to improve the existing product safety standards by informing the general public about potential dangers and creating a demand for safe products.

b) Market Review

WGO conducted face-to-face questionnaires in October and November 2016 with 200 Hong Kong parents who have children under the age of three. The market review was to determine the Hong Kong market for baby personal care products so that a sampling method can be decided.
Demographics: Below are graphs showing the demographic of the 200 Hong Kong parents.

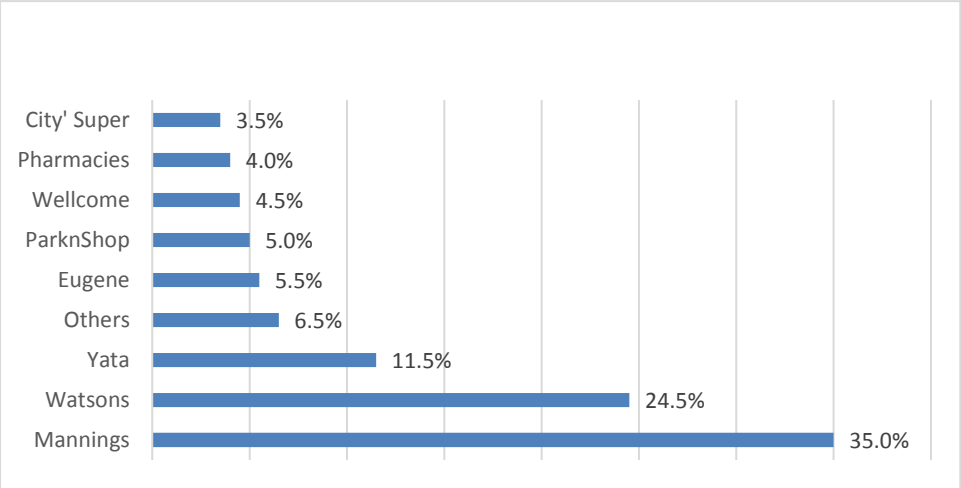




Findings:

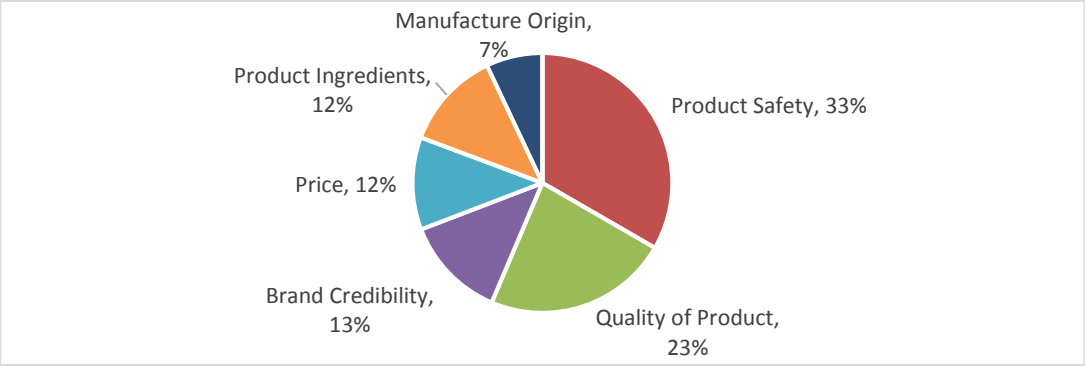
Hong Kong Market

Graph 1: Where Hong Kong parents buy their baby personal care products



From the graph above, 85% of respondents buy their baby personal care products at major retailers.

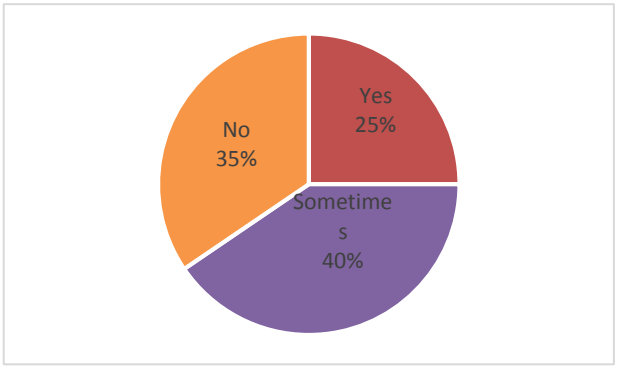
Graph 2: What Hong Kong parents look for when buying baby personal care products



From graph 2, other than the price, all the other categories are related to the safety of the product. This demonstrates that Hong Kong parents are interested in and concerned about the safety of the baby personal care product market.

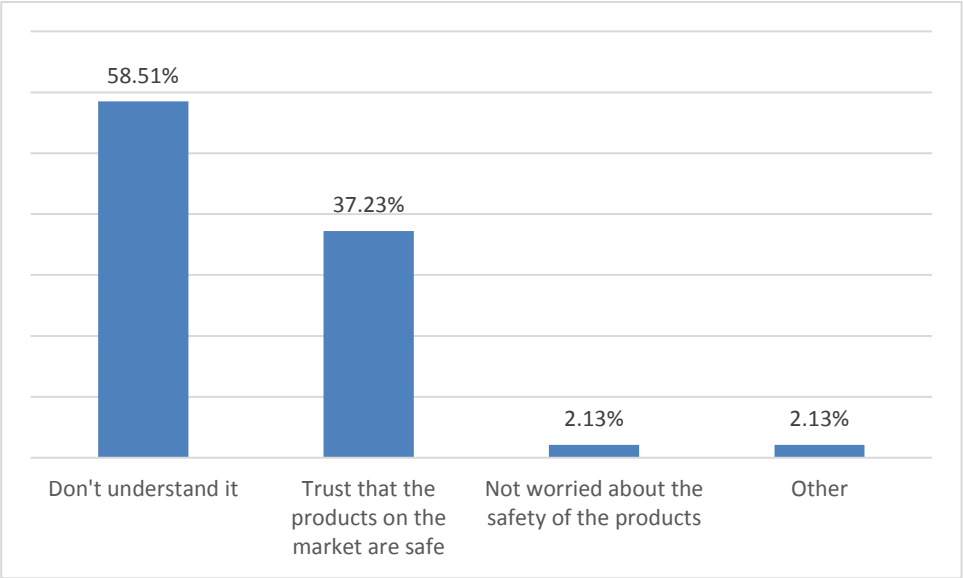
Safety awareness and knowledge of the Hong Kong parents

Graph 3: Percentage of respondents who read the ingredients label of their baby personal care products.



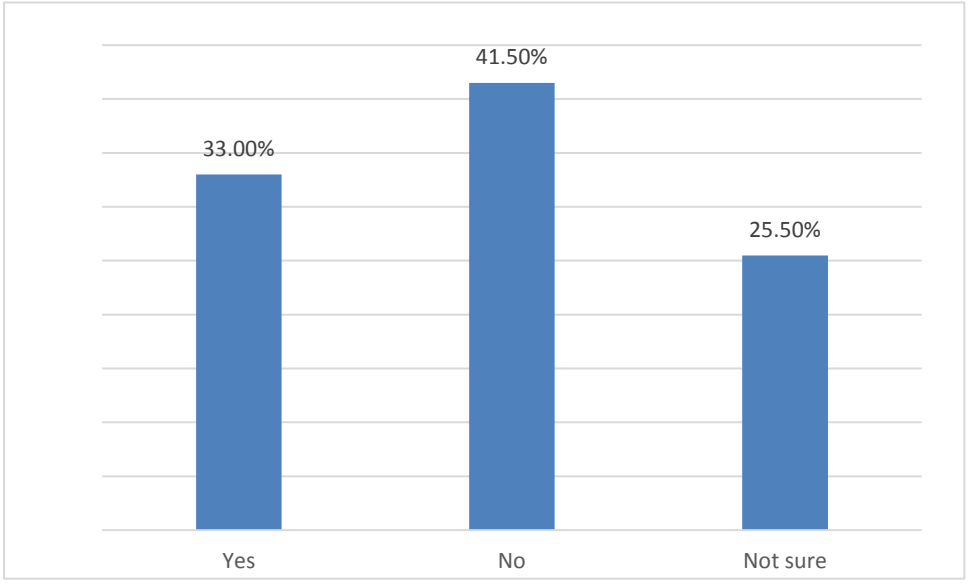
Only 25% of respondents always read the ingredients label to see what ingredients are in the products or to see if it is safe. This gives us a hint of the safety awareness gaps within the Hong Kong community.

Graph 4: Reasons why respondents did not read the ingredient label



Over 58% of respondents do not read the ingredient labels because they do not understand the words. This means that we need to raise safety knowledge of parents. Nearly 40% of the other respondents answered that they trusted the product safety. This tells us that we need to also raise public recognition to the potential health and safety threats

Graph 5: Percentage of Hong Kong parents who think that Hong Kong regulations are enough.
Only 1/3 of the respondents were confident about Hong Kong regulations. Over 41% of participants were



wary about Hong Kong regulations regarding product safety. This means that although some parents are concerned about the baby personal care product market, there is still a lot of work to be done in raising awareness of the gaps within product safety standards in Hong Kong.

These findings show a distinct lack of understanding and knowledge regarding baby personal care product safety. This confirms that we need to increase consumer awareness of baby personal care product safety in terms of the ingredients in the products, its health consequences, and government regulations.

c) Testing result analysis

Sampling:
We collected samples from the 7 leading retailers including City' Super, Eugene, Mannings Baby, ParknShop, Watsons Baby, Wellcome, and Yata for two major reasons.

1) Demand: In the market review, we found that 85% of respondents bought their baby personal care products from major retailers.
2) Supply: Major chain retailers are more likely to sell authentic products since their reputation relies on consumer trust.

Criteria: In order for products to be on the 'White List', they must pass all of the following criteria:

1) Biological: Products must pass Estrogenic Endocrine Disrupting Chemical (EDC) tests which analyse the way chemicals interact and affect the human body. (As mentioned before, endocrine disruptors are chemicals that negatively affect hormones in the human body and cause fatal health problems). In order to pass, products cannot exceed the amount of Estrogen Equivalent Concentration (EEQ) that is allowed. According to "Evaluations of the joint FAO/WHO expert committee on food additives (JECFA)" (2000, latest evaluation in 1999) on Estradiol-17beta, published by Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO), the acceptable daily intake (ADI) of Estradiol-17beta is 0-50 ng/kg bw[xv].

2) Chemical: Products must pass all chemical tests required for product safety. Heavy metals, methanol, and free formaldehyde levels must not pass regulations from the Safety and Technical Standards for Cosmetics, 2015 edition, China Food and Drug Administration (i) Heavy Metal Contamination - Part 1 General, Table 2 (3.4) Restricted Limit of Harmful Elements in Cosmetic Products. Baby skincare products cannot exceed the following:
    - Heavy metal
        a. Arsenic (As) ≤2mg/kg(ppm)
        b. Lead (Pb) ≤10mg/kg(ppm)
        c. Mercury (Hg) ≤1mg/kg(ppm)
        d. Cadmium (Cd) ≤5mg/kg(ppm)
    - Methanol ≤2000mg/kg(ppm)
    - Free formaldehyde ≤2000mg/kg(ppm)

3) Ingredient Checking: Products must not contain any chemicals that are associated with health complications, eco-toxicity, or contamination by scientific safety evaluations, or are banned by the following governmental agencies and authoritative bodies.
    - US: USFDA's 'Summary of colour additives for use in the United States in foods, drugs, cosmetics, and medical devices' and 'Prohibited & Restricted Ingredients'
    - EU: European Commission No. 1223/2009

- China: China FDA's 'Safety and Technical Standard for Cosmetics' (2015)
- Japan: Japan's 'Standards for Cosmetics' (2000)

These criteria are measured by:

1) EDC activity is evaluated by quantification of Estrogen Equivalent (EEQ) concentration in the product. This test is provided by Vitargent using their patented transgenic medaka eleutheroembryos assay. Sample extracts are obtained upon pre-treatment protocol and then exposed to estrogenic EDC-sensitive medaka eleutheroembryos for 24 hours. When estrogenic EDCs are detected, livers of the fish eleutheroembryos give off a green florescence light. The intensity of the light will be quantified and compared to the 17beta-estradiol dose response curve to calculate EEQ.

2) Chemical testing used several different testing methods. To test for heavy metals, the microwave digestion method (which increases both the speed of thermal decomposition and solubility of heavy metals in solution so that the heavy metals can be quantified) and Inductively Coupled Argon Plasma Mass Spectrometry (which detects metals and non-metal and quantifies them by ionising the sample and separating the ions) was used. Methanol analysis uses gas chromatography – flame ionisation detector (FC-FID) which measures the concentration of methanol in a gas stream. To test for free formaldehyde, an ultraviolet spectrophotometry (UV-VIS) which measures the attenuation of a beam of light after it passes through a sample due to absorption of a specific molecule, in this case – free formaldehyde was used.

3) Ingredient check uses the international guidelines and cross reference ingredients in the baby personal care products to make sure that they do not contain any banned ingredients.

Partners and Collaborators: Below are the official partner laboratories that are helping WGO conduct the biological, chemical, and ingredient checking tests.

WGO (project lead): The World Green Organisation (WGO) is an independent non-governmental organisation concerned with environmental conservation and environmentally related livelihood and economic affairs by proposing an integrated, three-pronged solution that combines social, environmental, and economic aspects, leading to an environmental revolution. Through science-based policy research and community projects, the WGO aims to enhance the quality of the environment, promote a greener economy, and improve people's livelihoods. In particular, it focuses on the social concerns of underprivileged groups and on the creation of a green economy, to help realise its vision of sustainable development.

VITARGENT (biological testing provider): Vitargent (International) Biotechnology Limited, established in October 2010, is an innovative bio-testing service provider with international award-winning transgenic medaka eleutheroembryo based Estrogen Equivalent Test as an alternative to animal testing. Vitargent's vision is to combine scientific expertise with social responsibility to improve consumer product safety and protect environment – "Smarter Testing, Safer Choices, Better World!" The company has served various internationally renowned cosmetics groups, food conglomerates, testing labs, universities and government bodies worldwide.

ALS HONG KONG (chemical testing provider)**:** Australian Laboratory Services (ALS) is the world's largest and most diversified analytical testing service provider. ALS delivers projects and services through four main operating divisions: Minerals (Geochemistry, Metallurgy, Mine Site and inspection), Life Sciences (Environmental, Food and Pharmaceutical, Animal Health and Electronics), Energy (Coal, Oil and Gas) and Industrial (Asset Care and Tribology). ALS is the global benchmark for quality and integrity, and we have built our reputation on quality, client service, innovation, and technical excellence. ALS Hong Kong's commitment to systemisation and standardisation allows our people to focus on what is important.

TÜV Rheinland (chemical testing provider): The TÜV Rheinland is a leading provider of technical services worldwide. Since our foundation in 1872, we have been providing safe and sustainable solutions for the challenges arising from the interaction between man, the environment and technology. As an independent, neutral and professional organisation, we are committed to working towards a future that can fulfil the needs of both mankind and the environment in the long-term.

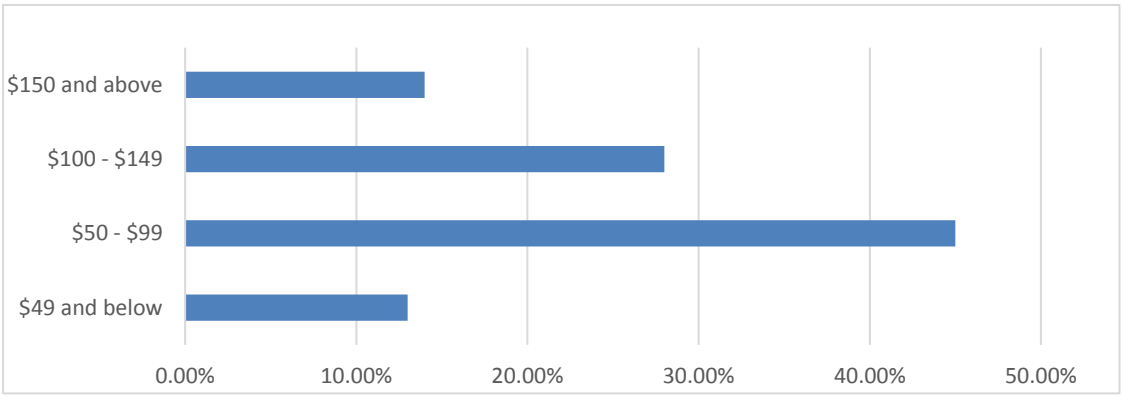
d) Product Type: Baby Lotion

Definition: "a liquid, usually aqueous or sometimes alcoholic preparation containing insoluble material in the form of a suspension or emulsion, intended for external application without rubbing, in suchskin conditions as itching, infection, allergy, pain, or the like".[xvi] In this study, we are differentiating lotion from cream by the packaging (bottle instead of a tub or jar) and name of the product.

Major Players include:

Global[xvii]	**Hong Kong**
Angel Baby	Aveeno (Johnson & Johnson)
Baby Ganics	BabyGanic
Burt`s Bees Baby	Burts Bee Baby
California Baby	Cetaphil
Johnson and Johnson	Chicco
Mustela/Laboratoires Expanscience	D&G Laboratories/Aleva Natural
Noodle and Boo	Johnson and Johnsons
Puracy	Mustela/Laboratoires Expanscience
Seventh Generation	Sebapharma

Price:
Graph 6: Preferred price range for a 200 ml baby lotion product:



From the graph above, parents are mostly willing to spend $50-$99 for a 200 ml baby lotion product. To accommodate consumers with different spending powers, we decided to differentiate the 'White List' by price.

e) White List

WGO's 'White List' includes only products that have passed EEQ tests, regulated chemical tests, and product ingredient checking. This 'White List' of products can act as a reference for new or existing parents when making a purchase (As mentioned before, this list is dynamic and is subject to change).

Baby Lotion 'White List':

Product		
HKD 50 – 99		
 Cow Soap Baby Milk Lotion	 Johnson's Baby Naturals Nourishing Lotion	
HKD 100 – 150		
 Chicco Baby Moments Body Lotion	 Aleva Naturals Daily Soothing Moisturizer	 Dr Brown's Baby Lotion

 Cetaphil Baby Daily Lotion with Shea Butter	 Live Clean(Baby) Soothing Relief Baby Lotion with soothing oatmeal and chamomile	 Baby's Herbal Garden Sweet Violet Baby Lotion
 Suanvinex Massage Body Lotion	 Sanosan Baby Care Lotion	 Marine Elements Dry Skin Management System, Body Lotion
 Avado Organics Baby Naturals Moisturiser	 Atopico Water Lotion	
HKD 151 and above		
 Atorrege ATORREGE AD+ Body milk	 Anumi Natural Soothe Me Tender Baby Lotion	 Atopalm Skin Barrier Function
 Love Boo Kind & Creamy Baby Lotion,	 Bubba Blue Australia Baby Moisturiser	 Baby Bee Baby Bee Nourishing Lotion
 California Baby Super sensitive, Everyday Lotion	 CNP Laboratory Face & Body Moisturizer	 Palmer's Cocoa Butter Formula with Vitamin E, Baby Butter
 Mustela Stelaprotect Body milk	 Gaia Natural Baby Pure, Nature, Organic, Skin Soothing Lotion	 Eco Kid, Certified Organics for Kids, Potion Lotion

 Mambino Baby's BestDaily Essential Lotion	 Greenicare Organic Baby Moisturizing Lotion		SWISSNATURLICH Baby Dreamy Lotion
 Derma+care Nurturing Lotion for Baby	 First Light Organics for Baby		

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[i] https://www.epa.gov/chemical-research/research-evaluating-chemicals-adverse-effects

[ii] https://books.google.com.hk/books?id=-aQQAqW2YKYC&pg=PA273&lpg=PA273&dq=USEPA+87000+identify&source=bl&ots=6bfwQo2KEn&sig=Hnjjl6VRXUnxpEecQQ7EhnHmUiw&hl=en&sa=X&ved=0ahUKEwipm6z98ZjQAhUBzbwKHQ8GCIsQ6AEIKjAD#v=onepage&q=USEPA%2087000%20identify&f=false

[iii] http://www.mintel.com/press-centre/household-press-centre/baby-household-products-almost-double-over-past-five-years-globally

[iv] http://www.who.int/ipcs/publications/en/ch1.pdf?ua=1

[v] http://www.ewg.org/enviroblog/2014/01/chemicals-should-disappear-cosmetics

[vi] http://www.webmd.com/children/features/personal-care-products

[vii] http://www.simpleluxeliving.com/the-environmental-damages-of-cosmetics/

[viii] https://ec.europa.eu/growth/sectors/cosmetics/legislation_en

[ix] http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm

[x] http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm2005209.htm

[xi] http://www.cirs-reach.com/Cosmetics_Registration/China_cosmetics_regulations_registration.html

[xii] http://www.mhlw.go.jp/english/dl/cosmetics.pdf

[xiii] http://cdnsite.eu-japan.eu/sites/default/files/publications/docs/cosmetics-japan.pdf

[xiv] http://www.info.gov.hk/gia/general/201402/19/P201402190332.htm

[xv] http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=1835

[xvi] http://www.dictionary.com/browse/lotion

[xvii] http://www.prnewswire.com/news-releases/global-baby-toiletries-industry-300321126.html