



Licence to Manufacture Therapeutic Goods - Part 1

Licence Number:
MI-2019-LI-02603-1

TGA licenced under GMP Pic Guide 13 – Lic# MI-2019-LI-02603-1



Licence to Manufacture Therapeutic Goods - Part 2

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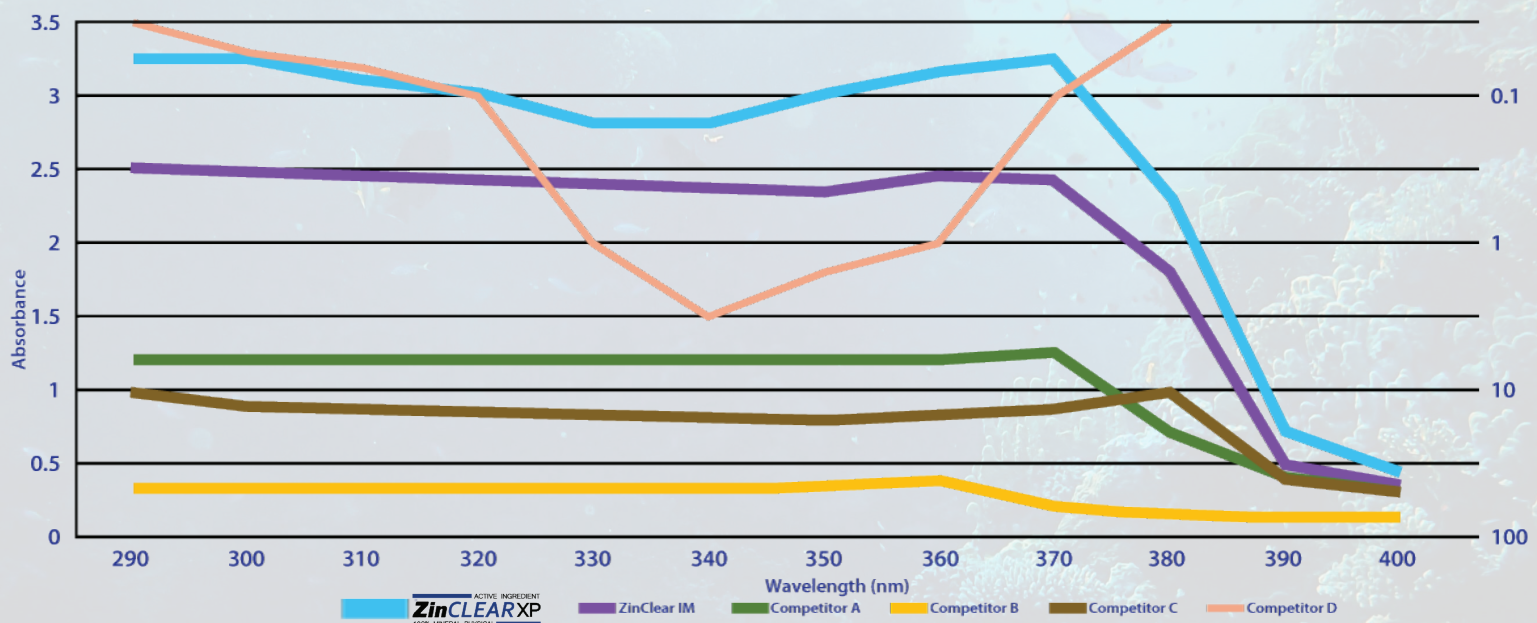


Lic# 1206750

LISTED AS APPROVED MANUFACTURER BY FDA

“ZnO NPs have emerged a promising potential in biomedicine, especially in the fields of anticancer and antibacterial fields” <https://www.hindawi.com/journals/bca/2018/1062562/>

ACTIVE INGREDIENT
ZinCLEARXP/XPC Powder Performance versus Competitors
100% MINERAL PHYSICAL



- 6 Vegan/Natural Zinc Oxide & Zinc Oxide Based Powders**
- 4 Vegan/Natural Zinc Oxide & Zinc Oxide Based Dispersions**
- 4 Vegan Classic Zinc Oxide & Zinc Oxide Based Dispersions**
- 4 Vegan Bulk SPF 50+ Rated Intermediate Sunscreen**

Products (under development) Products approved by ECOCERT suitable to be used in organic products.

Some Natural Dispersions Contain Alusion

3 SPF50 FDA/TGA Approved End Formulations

(License Agreement available to use these recipes)

**“32 various skin cancer procedures -
For me it’s not just business, it’s PERSONAL”**

Managing Director Geoff Acton



100% Uncoated Natural Non-Nano Zinc Oxide

Sunscreen Benefits (not found in coated zinc oxide)

UVA / UVB BROAD SPECTRUM PROTECTION

"Of the available sunscreens, only zinc oxide provides effective protection across the UV band range of 240 to 400 nm, covering UVC (240 to 280 nm), UVB (280 to 320 nm), UVA 2 (320 to 340 nm), and UVA 1 (340 to 400 nm). [9]

- "UVA rays account for 95% of our sun exposure. They cause skin aging and contribute to skin cancer." [10]
- "The risk for skin cancer doubles in people who have had five or more sunburns." [10]
- "UVA rays penetrate deeply into the skin layers, damaging collagen and cells which leads to wrinkling, hyperpigmentation and loss of elasticity." [10]
- "UVB rays mostly affect the outer layer of the skin." [10]

Zinc Oxide Benefits

- "Treatment with both types of uncoated ZnO nanoparticles mobilised pathways and responses centred on cellular stress, survival and apoptosis." [11]
- "A new study led by two Australian universities has found evidence that zinc oxide nanoparticles used in sunscreen does not cause cellular toxicity even after repeated applications." [12]
- "The levels we found in blood were very small," says McCall, a research consultant on nano0safety at CSIRO. "After applications over five days, the levels of the tracer zinc in the blood were one thousandth of what is the naturally-occurring total zinc levels in the blood." [13]

Pregnancy and Child Safety

- "Zinc is known to play a critical role in biological processes including cell growth, differentiation and metabolism and deficiency in this micronutrient restricts childhood growth and decreases resistance in infections, which contribute significantly to morbidity and mortality in young children." [15]
- "In 2011, it was estimated that 116, 000 child deaths per year are attributable to zinc deficiency." [16]

Powders and Some Dispersions are Available as Vegan & Natural

- "6,581,298 vegans in the USA (2019)" [20]
- "30,733,152 vegans in only 14 countries counted" [20]
- "The global natural cosmetics market size is expected to reach a value of USD 48.04 Billion by 2025, increasing by 5.04% from 2019 to 2025, according to a recent report published by Grand View Research." [21]

Reef Safe

- "Zinc (Zn) is a necessary micronutrient in the ocean" [22]
- "Dissolved Zn may therefore be an important control of distributions of surface productivity and the efficiency of the global carbon cycle." [23]
- "The limited supply of Zn to the surface Atlantic Ocean can explain the lack of an Atlantic Zn remineralization signal and indicates Zn might play a role in phytoplankton community composition and productivity." [24]

Cruelty Free

- "Animals such as rabbits, rats, mice, and guinea pigs are sometimes forced to eat or inhale substances, or have a cosmetic ingredient rubbed onto their shaved skin, eyes or ears every day for 28 or 90 days to see if they have an allergic reaction. Then they are killed and cut open to examine the effects the ingredient has on internal organs. These tests are also done with pregnant animals who, after much suffering, are killed along with the fetus." [26]

9. <https://www.spiedigitallibrary.org/journals/journal-of-biomedical-optics/volume-25/issue-1/014509/Noninvasive-in-vivo-human-multiphoton-microscopy--a-key-method/10.1117/1.JBO.25.1.014509.full?SSO=1>
10. <https://heartland-derm.com/skin-cancer-prevention/>
11. <https://www.longdom.org/open-access/surface-coatings-protect-against-in-vitro-toxicity-of-zinc-oxide-nanoparticles-2157-7439.1000232.pdf>
12. <https://www.cosmeticsdesign-asia.com/Article/2019/01/23/Australian-study-supports-the-use-of-zinc-oxide-nanoparticles-in-sunscreens>
13. <https://www.abc.net.au/science/articles/2012/11/30/3642924.htm>
15. https://www.who.int/elena/bbc/zinc_stunting/en/
16. <https://academic.oup.com/ajcn/article/111/4/927/5815488>
20. <https://static1.squarespace.com/static/56424f6ce4b0552eb7fdc4e8/t/575f4247859fd09b4e482b5d/1465860680024/Low-Risk-of-Adverse-Effects-from-Zinc-Supplementation.pdf>
21. <https://en.wikipedia.org/wiki/Veganism>
22. <https://beautybusinessjournal.com/the-organic-cosmetics-market-is-growing-naturally/>
23. <https://www.sciencedirect.com/science/article/pii/S0166445X19306381>
24. <https://agupubs.onlinelibrary.wiley.com/doi/pdf/10.1002/2014GB004862>
26. <https://www.sciencedaily.com/releases/2020/09/200902091112.htm>

Hypoallergenic

- "A study in Denmark, 56.7% of women (3,288,600 million) and 33.6% of men (1,948,800 million) in Denmark have experienced an adverse effect after using cosmetics at least once." [27]
- "In a study in which a 25% zinc oxide patch (2.9mg/cm²) was placed on human skin for 48 hours, there was no evidence of dermal irritation." [28]
- "In another study comparing the dermal effect of different zinc compounds in mice, rabbits and guinea pigs, zinc chloride was clearly the strongest irritant, followed by zinc acetate, causing moderate and zinc sulfate, causing low irritations. Consistent with the study of Agren, zinc oxide did not show any irritant effect on skin." [28]

Skin Vitality

- Zinc is needed for building keratin and for the formation of the skin's structural protein – collagen. In fact, collagen in the skin is produced by zinc-dependent enzymes called collagenases. Zinc is essential not only for the enzymes producing type 1 and type 3 dermal collagen but also for the cross-linking that gives collagen its durability and stability. Human studies have shown that decreased zinc results in decreased total collagen. [30]
- Topical zinc therapy is underappreciated even though clinical evidence emphasizes its importance in autodebridement, anti-infective action, and promotion of epithelialization. [31]
 - Autodebridement: 'self' removal of dead/damaged/infected tissue [31]
 - Epithelialization: Proliferation of skin cells [31]
- "Because zinc acts as an enzyme cofactor, it assists in collagen synthesis and DNA repair, which can help keep skin looking younger and healthier." [32]

Zinc Oxide Anti-bacterial & Wound Healing

- "Zinc had been used during the regime of Pharaohs, and historical records show that Zinc Oxide was used in many ointments for the treatment of injuries and boils even in 2000 BC" [33]
- "Of all natural and synthetic wound dressing materials, the chitosan hydrogel microporous bandages laced with zinc oxide nanoparticles developed by Kumar Etal are highly effective in treating burns, wounds and diabetic foot ulcers" [33]

Zinc Oxide Deficiency

- "Worldwide, about two billion (~2,000,000,000) people are estimated to be affected by zinc deficiency." WHO (2017) [34]
- "According to the WHO, zinc deficiency is currently the fifth leading cause of mortality and morbidity in developing countries" [35]
- "There is strong evidence between zinc deficiency and several infectious diseases such as malaria, HIV, tuberculosis, measles, and pneumonia." [36]
- "Worldwide, zinc deficiency is responsible for approximately 16% of lower respiratory tract infections, 18% of malaria and 10% of diarrhoeal disease." [37]
- "In total, 1.4% (800,000) of deaths worldwide were attributable to zinc deficiency: 1.4% in males and 1.5% in females." [38]
- "Attributable DALYs (Disability Adjusted Life Years) were higher, with zinc deficiency accounting for about 2.9% of worldwide loss of healthy life years." (2.2 Years) Potential 2.42 Billion Life Years" [39]

Gluten Free

- "In 2017, the number of Americans going Gluten- Free has tripled since 2009." [40]
- "In 2017, 3.1 million people across the United States follow a gluten-free diet. 72 percent of them are classified as "PWAGs" - people without celiac disease avoiding gluten" [40]

27. <https://en.wikipedia.org/wiki/Cruelty-free>

28. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3858659/>

30. <https://aestheticmed.co.uk/site/featuresdetails/the-effect-of-zinc-on-skin>

31. Zinc in wound healing: Theoretical, experimental, and clinical aspects - Lansdown - 2007 - Wound Repair and Regeneration - Wiley Online Library

32. Zinc for Skin: The Complete Guide (byrdie.com)

33. <https://nanoscalereslett.springeropen.com/articles/10.1186/s11671-018-2532-3>

34. <https://www.who.int/whr/2002/chapter4/en/index3.html>

35. <https://www.mdpi.com/2072-6643/9/6/624/htm#:~:text=According%20to%20the%20WHO%2C%20zinc%20deficiency%20is%20currently,18%25%20of%20malaria%2C%20and%2010%25%20of%20diarrheal%20diseases>

36. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490603/>

37. <https://www.who.int/whr/2002/chapter4/en/index3.html>

38. <https://www.who.int/whr/2002/chapter4/en/index3.html>

39. <https://www.nimh.nih.gov/health/statistics/global/index.shtml#:~:text=The%20burden%20of%20disability%20associated,death%20within%20a%20given%20population>

40. <https://www.forbes.com/sites/niallmccarthy/2017/01/17/the-number-of-americans-going-gluten-free-has-tripled-since-2009-infographic/#42ea90e832f2>

28% of consumers said the move to online shopping in light of Covid lockdowns made them more likely to buy organic beauty and wellbeing products. [91]

Health effects from solar UVR

- ARPANSA and other national and international health authorities, including the World Health Organization have assessed that overexposure to ultraviolet radiation (UVR) causes eye damage, sunburn, tanning and other skin damage that can ultimately result in skin cancer. [95]
- 40% more material must be applied to the skin for SPF 30 product to achieve same protection as SPF 50 product.

ANO Timeline (ASX announcements) Company Performance FY17 to now - trading results / powder production / sales

1987 - MCP technology starts at University of Western Australia using Ball Mill technology.

1997 - Company formed to develop the UWA potential MCP technology after successful trials.

2000 - Joined with Samsung Corning to develop production scale MCP technology.

2002 - ZinClear products first launched DOW market presentation.

2005 - ANO lists on ASX - UWA owns 62 million shares.

2009 - Merck signs exclusive agreement with Antaria for sale of Alusion.

2010 - UWA owns 20.4%
- Ankla Pty Ltd owns 9.3% (company related to current Chairman, Lev Mizikovsky)
- **Market capitalisation \$8.12 million**

2010 - Tax losses of \$33 million.

2017 - Pre-cursor raw material shortage will be rectified by 1st week of April of 2017 when 24 tonnes arrives in the warehouse and we currently have approximately \$900,000 of sales orders ready to invoice and ship once we complete the rigorous testing regime.
- The current capitalisation as of yesterday is \$31.6 million.

2019 - We have witnessed significant growth in the sales of XP Powder, particularly in the USA, with one customer ordering six times (up 500%) more volume of orders from the prior year.
- Current production of 15T per week (from 7T per week FY17).
- Lift production to 40T in late 2019, annual capacity of 2,200T.

2020 - The Board has been informed by our US distributor that over 50% of its original 180T stock holdings in XP powder has been sold in the past 4 months.
- Still on track for our TGA audit in February / March 2021 as previously announced in the recent COVID update announcement.
- **ANO Milestones 2021 including a listing on NASDAQ in January 2022.**

2021 - Market capitalisation of \$259 million.

Non Nano Statements

Our product has been tested by external university and proven to be Non Nano

STA901.105_R1

ZinClear Australian & New Zealand Non-Nano Statement

Australia

The Australian Government Department of Health and Ageing – NICNAS 2010, defines a nanomaterial as: "Industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm to 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale). Aggregates and agglomerates are included and apply to materials where 10% or more of the particles by number count meet the above definition."

In a Literature Review on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreens published by the Therapeutic Goods Administration of Australia in August 2016, nanoparticles are defined as "materials within the nanosize range of 1 to 100 nm."

New Zealand

As stated in the Cosmetic Products Group Standard 2017 – HSR002552, the New Zealand Government of Environmental Protection Authority define a nanomaterial as: "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm."

Our ZinClear product range is **non-nano**, according to the above definitions.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our ZinClear range of products.


Geoff Acton, B. Com. CA
Managing Director

Effective from 03 November 2020

Latest revision supersedes previous document revisions

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an advanced materials world

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STA901.94_R3

ZinClear European Non-Nano Statement

French decree n°2010-232 issued on 17.02.2012

In regard to the French nanomaterial decree n°2012-232, a nanomaterial is defined in article 3 of Regulation (EC) n°1907/2006 (REACH) as a substance intentionally manufactured at nanoscale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm and 100 nm.


Our ZinClear product range is **non-nano** according to the above definition.

Cosmetic regulation EC 1223/2009

In regard to the Cosmetic Regulation EC 1223/2009, a nanomaterial is defined as an *insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.*

Our ZinClear product range is **non-nano** according to the above definitions.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our ZinClear range of products.


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STA901.74_R1

ZinClear US Non-Nano Statement

In the US there is no current legal definition of what constitutes a nanoparticle as stated by the FDA. In June 2014, FDA issued a guidance for industry titled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology". As described in that guidance, when considering whether an FDA-regulated product involves the application of nanotechnology, the FDA will ask: (1) whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale (approximately 1 nm to 100 nm); and (2) whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if the dimensions fall outside of the nanoscale range, up to (1,000 nm).

There are however, other government bodies outside of the US that make such statements.


The French decree n°2010-232 issued on 17.02.2012 defined a nanomaterial in article 3 of Regulation (EC) n°1907/2006 (REACH) as "a substance intentionally manufactured at nanoscale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range of 1 nm and 100 nm"

The Cosmetic Product Group Standard 2017 – HSR002552 of New Zealand Government Environmental Protection Authority defines nanomaterial as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm".

In a literature review on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreens published by the Therapeutic Goods Administration of Australia in August 2016, nanoparticles are defined as "materials within the nanosize range of 1 to 100 nm".

According to these definitions, our range of ZinClear Products are considered to be **non-nano**.

Additionally, no raw materials created by nanotechnology are used in the manufacturing process of our ZinClear range of products.


Geoff Acton, B. Com. CA
Managing Director

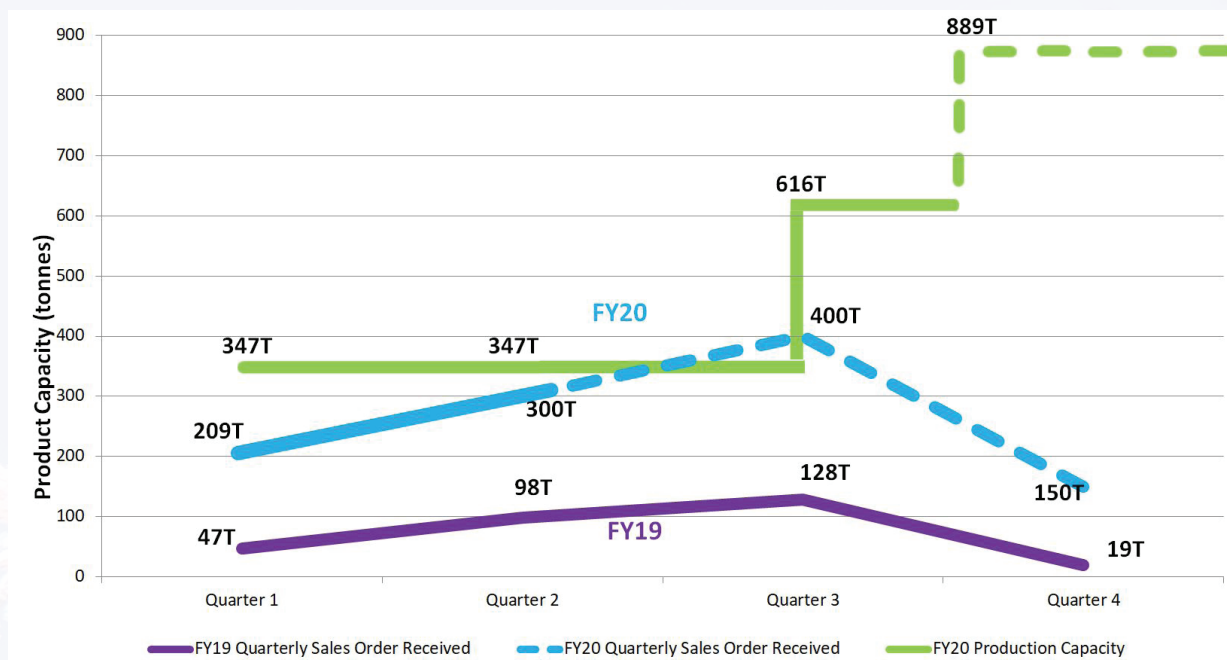
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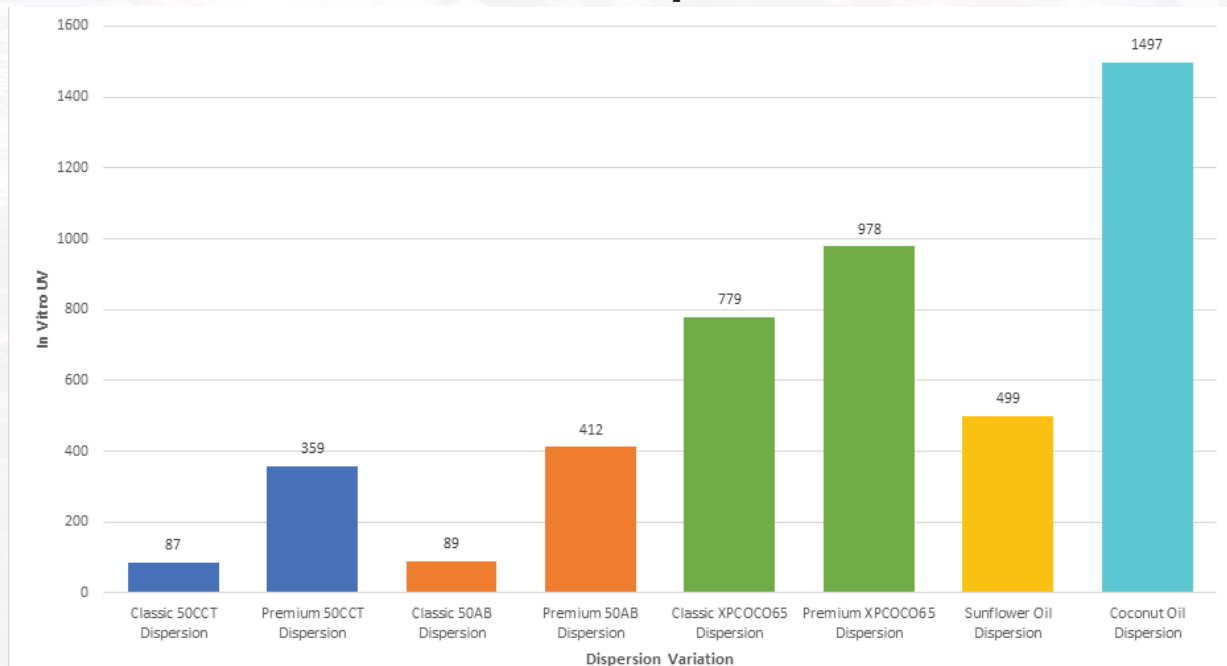
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Quarterly Sales Orders Vs Quarterly Production Capacity



These sales figures (2019/20 projection) are based on the current pace of sales orders and are a guide only.

In Vitro UV Measurements for Dispersion Variations



The high in vitro UV values correlate to the high concentration of zinc oxide present in the dispersion and are not reflective of the SPF in final products.

The Premium Dispersions vary due to differences in the manufacturing process and equipment.

Applications of Zinc Oxide

- Zinc Oxide is used in sunscreen products – UVA and UVB protection.
- Zinc Oxide is a potent antioxidant and a good substantivity when used in the oral cavity.
- Zinc Oxide is effective against plaque- and caries-forming bacteria.
- Zinc Oxide has an anti-staph bactericidal effect.
- Zinc Oxide is active against streptococci by blocking the synthesis of their energy molecules. [96]
- Zinc Oxide is effective against *Fusobacterium Nucleatum* and *Prevotella intermedia*: the two main bacteria that cause gingivitis.
- Zinc Oxide is an essential component of teeth. It is more concentrated in the superficial layer of the enamel.
- Zinc Oxide also helps maintain oral bone health.
- Zinc Oxide helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.
- Zinc Oxide dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Antaria Powders & Dispersions do NOT use the following ingredients

Chemical UV Filters Banned or proposed to be Banned:

	Octinoxate	Avobenzene	Oxybenzone (BP-3)	Methylbenzylidene Camphor	Homosalate	Octocrylene
Countries:	Australia					
	Hawaii	×	×	×	×	×
	Palau	×	×	×		
	Bonaire	×	×			
	USA			×		
	Marshall Islands	×	×	×	×	×
	Japan		×	×	×	
	Sweden		×	×		
	U.S Virgin Islands		×	×		×
	Aruba		×			
	Nature Reserves Mexico	×	×	×	×	×
	Thailand	×	×	×	×	×

[37,38,39,40,41,42,43,44,45,46,47,48]

37. <https://www.who.int/whr/2002/chapter4/en/index3.html>
38. <https://www.who.int/whr/2002/chapter4/en/index3.html>
39. <https://www.nlm.nih.gov/health/statistics/global/index.shtml#:~:text=The%20burden%20of%20disability%20associated,death%20within%20a%20given%20population>
40. <https://www.forbes.com/sites/niallmccarthy/2017/01/17/the-number-of-americans-going-gluten-free-has-tripled-since-2009-infographic/#42ea90e832f2>
41. <https://www.staradvertiser.com/2020/01/30/breaking-news/hawaii-bills-would-limit-more-than-a-dozen-chemicals-in-sunscreens/>
42. <https://stream2sea.com/the-republic-of-palau-adopts-the-worlds-strictest-national-sunscreen-standard/>
43. <https://www.livescience.com/62598-bonaire-island-bans-sunscreen.html>
44. <https://www.bbc.com/news/science-environment-46046064>
45. <https://www.beauty-heroes.com/blog/villain-ingredient-concern-chemical-sunscreens/>
46. <https://abcnews.go.com/International/sunscreen-pollution-accelerating-demise-coralreefexpertsstory?id=68807099>
47. <https://www.divesmartgozo.com/sunscreen-damaging-coral-reefs/>
48. <https://www.latimes.com/travel/story/2019-08-27/us-virgin-islands-ban-on-harmful-sunscreens-to-go-into-effect-jan-1>

Harmful Effects of UV Chemical Filters to Adults, Children and Babies

Chemical	Hormone Disruption	Reproductive & Developmental Toxicity	Systemic Absorption & Accumulation	Photo-contact Allergy & Dermatitis	Nervous System Effects
Octinoxate	✗ [67-70]	✗ [69]	✗ [71]		
Oxybenzone	✗ [67, 68, 72]	✗ [73]	✗ [71]	✗ [74]	
Methylbenzylidene Camphor	✗ [67, 72, 73, 76]	✗ [73, 77]		✗ [78]	
Homosalate	✗ [72, 79]		✗ [71]		
Octocrylene			✗ [71]	✗ [80]	
Avobenzene*					
Methylparabens	✗ [81, 82]	✗ [83 - 85]			
Phenoxyethanol				✗ [86, 87]	✗ [88]

* Avobenzene is unstable under sunlight and must be formulated with other chemical UV filters to stabilise it, and thus carries their risks.

67. Schlumpf, M. et al. In vitro and in vivo estrogenicity of UV screens. *Environ. Health Perspect.* 109, 239–244 (2001).
68. Kunz, P. Y. & Fent, K. Multiple hormonal activities of UV filters and comparison of in vivo and in vitro estrogenic activity of ethyl-4-aminobenzoate in fish. *Aquat. Toxicol.* 79, 305–324 (2006).
69. Axelstad, M. et al. Effects of pre- and postnatal exposure to the UV-filter octyl methoxycinnamate (OMC) on the reproductive, auditory and neurological development of rat offspring. *Toxicol. Appl. Pharmacol.* 250, 278–290 (2011).
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79. Ma, R. UV Filters with Antagonistic Action at Androgen Receptors in the MDA-kb2 Cell Transcriptional-Activation Assay. *Toxicol. Sci.* 74, 43–50 (2003).
80. Berardesca, E., Zuberbier, T., Sanchez Viera, M. & Marinovich, M. Review of the safety of octocrylene used as an ultraviolet filter in cosmetics. *J. Eur. Acad. Dermatology Venereol.* 33, 25–33 (2019).
81. Darbre, P. D. & Harvey, P. W. Paraben esters: review of recent studies of endocrine toxicity, absorption, esterase and human exposure, and discussion of potential human health risks. *J. Appl. Toxicol.* 28, 561–578 (2008).
82. Taxvig, C. et al. Do Parabens Have the Ability to Interfere with Steroidogenesis? *Toxicol. Sci.* 106, 206–213 (2008).
83. Kang, K.-S. et al. Decreased Sperm Number and Motile Activity on the F1 Offspring Maternally Exposed to Butyl p-Hydroxybenzoic Acid (Butyl Paraben). *J. Vet. Med. Sci.* 64, 227–235 (2002).
84. Kawaguchi, M. et al. Maternal isobutyl-paraben exposure alters anxiety and passive avoidance test performance in adult male rats. *Neurosci. Res.* 65, 136–140 (2009).
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86. Chasset, F. et al. Contact dermatitis due to ultrasound gel: A case report and published work review. *J. Dermatol.* 43, 318–320 (2016).
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Dangerous Chemical Filters When Mixed with Swimming Pool Water

Avobenzene / Oxybenzone

- "Scientists from the Faculty of Chemistry of the Lomonosov Moscow State University have demonstrated in their research the nature of hazardous chemical compounds formed as a result of the breakdown of avobenzene, a component of many sunscreen products, when it interacts with chlorinated water and ultraviolet radiation." [1]
- "The photo-instability of organic UV filters is recognized as a major problem, since they lose their photo-protective properties and generate photoproducts that may cause allergies or other harmful effects." [2]
- "What is more concerning is the fact that chlorinated products are formed very fast and some of them were found in swimming pool waters during summer season when a high number of people visit and enjoy this area." [2]

Avobenzene

- "One hour of sunlight exposure reduces avobenzene UV absorbance by 36%." [3]
- "Avobenzene suppresses proliferation and induces apoptosis in human trophoblast cells" [4]
- "Emerging evidence suggests that short-lived chemicals, particularly select phthalates and UV filters may be associated with endometriosis." [5]
- "It can degrade into some very harmful compounds, some of which are known carcinogens," said Daniel Aires, a dermatologist with the University of Kansas Health System." [92]
- "When exposed to chlorinated water, more toxic compounds are created." [92]
- As avobenzene degrades, which may be in less than two hours, it is no longer effective (or at least far less effective) at protecting you from UVA rays. You'll never know it though, because UVAs don't cause burns. They'll just get you decades later with wrinkled skin and cancer." [92]

Oxybenzone (BP-3)

- "Oxybenzone is a ultraviolet (UV) absorber used in 70% of sunscreen products, is a recognized endocrine disrupting chemical (EDC) and is small enough to pass through skin and placenta barriers." [6]
- "Liver and kidney weights were affected after both dermal and oral exposure to BP-3" [7]
- "BP-3 reacts with chlorine and produces hazardous by-products, such as bromoform, bromal hydrate and dibrominated BP-3, threatening human health" [56]

Titanium Dioxide

- "In 2019, France banned the use of titanium dioxide in food from 2020." [53]
- "The FDA have maintained that there are only two safe ingredients (GRASE) for sunscreen manufacture – zinc oxide and titanium dioxide. The EU released a statement that will require all labels with >1% titanium dioxide "as a category 2 suspected carcinogen by inhalation under EU regulations (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures" from September 9, 2021". [54]
- "Several studies show that nano-TiO₂ induces genotoxic effects, including DNA damage, and micronuclei formation that is indicative of chromosomal aberrations in different cell lines." [55]

1. <https://phys.org/news/2017-06-sunscreen-creams-dangerous-chemical-compounds.html>
2. <https://journals.matheo.si/index.php/ACSi/article/view/170/110>
3. https://www.researchgate.net/publication/281789531_In-vitro_Assessment_of_Effectiveness_and_Photostability_Avobenzene_in_Cream_Formulations_by_Combination_Ethyl_Ascorbic_acid_and_alpha_Tocopherol_Acetate
4. <https://www.sciencedirect.com/science/article/abs/pii/S0890623818300984>
5. <https://www.sciencedirect.com/science/article/pii/S0013935114002850>
92. <https://www.kitchenstewardship.com/uva-protection-probably-isnt-working/>
6. <https://www.sciencedirect.com/science/article/abs/pii/S0890623818305835>
7. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2605.2012.01280.x>
53. https://en.wikipedia.org/wiki/Titanium_dioxide
54. <https://www.fas.usda.gov/datafrance-france-bans-titanium-dioxide-food-products-january2020#:~:text=France%20announced%20a%20ban%20the,workers%2C%20consumers%20and%20the%20environment.>
55. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3423755/>
56. https://www.researchgate.net/publication/337641616_In_vitro_metabolism_of_sunscreen_compounds_by_liquid_chromatography-high_resolution_tandem_mass_spectrometry

Silicon

- "For acne-prone, silicones can act as a "barrier" and trap oil, dirt, and dead skin cells, making acne worse" [57]
- "Silicones may block subsequent ingredients from reaching the skin, rendering anything applied after a silicone product pretty much useless" [57]

Sulfate

- "The main direct effect of sulfates on the climate involves the scattering of light, effectively increasing the Earth's albedo." [58]
- "Health: Sulfate can irritate eyes, skin and lungs, especially with long term use. Sulfate may also be contaminated with a substance called 1,4-dioxane, which is known to cause cancer in laboratory animals. This contamination occurs during the manufacturing process." [59]
- "Sulfates may clog pores and cause acne." [59]

Paraben

- "Multiple studies have linked chlorinated parabens to endocrine disrupting functions, specifically mimicking the effects of estrogen, and chlorinated parabens are believed to be 3–4 times more toxic than their parent paraben." [60]
- "In 2016, 30% of French women associated organic and natural cosmetics as paraben free." [61]

Sunscreens become carcinogenic if left on the shelf for 1 year

- Some of the world's most popular sunscreens risk causing cancer if left on the shelf too long because a commonly used sun protection factor breaks down into a harmful ingredient, top US and French researchers claim. [89]
- However, a Franco-American study published in the Chemical Research in Toxicology review on Monday found that if left for a year at room temperature, such products become potentially toxic as one of their key ingredients breaks down into a product called benzophenone, which they say is a "mutagen, carcinogen, and endocrine disruptor". [89]

Harmful Preservatives

- "Phenoxyethanol is harmful if swallowed, inhaled or absorbed through skin, especially to nursing mothers or infants. Phenoxyethanol can have an effect on the brain and the central nervous system. It irritates skin and eyes, and can cause blistering on skin as well." [62]
- "Methylparabens (Hydroxybenzoates) are responsible for disrupting estrogenic and androgenic receptors, suggesting that parabens may have estrogenic and antiandrogenic effects in the prostate." [63]

Spray on Sunscreen

- "Energizer Personal Care has expanded its recall of continuous spray sun care products (see list below) in Canada because there is a possibility that these sunscreens could ignite on the skin if the consumer comes into contact with an open flame or spark before the spray has completely dried. One such case has been reported in Canada and four in the U.S." [64]
- "Avoid sunscreen sprays. They may be convenient, but they also pose a risk of exposing your child's lungs to potentially toxic chemicals. They also may not effectively coat the skin to offer the same protection as cream based formulas. Currently the FDA is investigating the safety of sunscreen sprays." [65]
- "6 Reason Why You Should Never Use Spray Sunscreen [66]
 - o Inhalation of Sunscreen Ingredients is Dangerous and Nearly Impossible to Avoid
 - o The Chemical Ingredients Are Linked To Health Issues
 - o Inadequate Coverage = Inadequate Protection
 - o People Have Caught on Fire After Applying Spray Sunscreen
 - o Swimming Pools and Sunscreen: New Research
 - o Environmental Concerns

57. <https://www.healthline.com/health/beauty-skin-care/silicones>

58. <https://en.wikipedia.org/wiki/Sulfate>

59. <https://www.healthline.com/health/beauty-skin-care/sulfates>

60. <https://en.wikipedia.org/wiki/Paraben>

61. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3858659/>

62. <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet>

63. <https://pubmed.ncbi.nlm.nih.gov/28181406/>

64. <https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15864a-eng.php>

65. <https://naturopathicpediatrics.com/2017/06/14/safe-natural-sunscreens-sun-safety-children/>

66.

<https://safebabyhealthychild.com/6-reasons-why-you-should-never-use-spray-sunscreen/>

89.

<https://elmoudjaweb.com/top-brand-suncreams-become-carcinogenic-if-left-on-the-shelf-too-long-claim-french-researchers-jaweb/>

The chemicals in sunscreen seep into your bloodstream after just one day

- The chemicals in sunscreen don't just sit on top of the skin, they absorb in the bloodstream, according to new research from the U.S. Food and Drug Administration. [94]
- A study published Monday in the peer-reviewed medical journal JAMA found that several active ingredients in different sunscreens enter the bloodstream at levels that far exceed the FDA's recommended threshold without a government safety inspection. [94]
- For all ingredients, the levels of all chemicals far exceeded that limit on the first day of the study. [94]
- Three of the ingredients remained in the bloodstream for seven days. [94]
- For oxybenzone, which has been found along with other sunscreen ingredients in breast milk, plasma concentrations reached the threshold within two hours after a single application and exceeded 20 ng/mL on day 7 of the study. [94]

Freshwater Ecosystems Safety

- "The results show that long-term exposure to ultraviolet (UV) filters -- including avobenzone, oxybenzone, and octocrylene -- is lethal for some organisms living in freshwater environments. One of the largest sources of UV-filter contamination in both marine and freshwater environments is from sunscreen leaching off of the skin while swimming." [25]

UV Chemical Sunscreens Bans

- "State lawmakers passed legislation in May that would ban skin-care companies from selling and distributing sunscreens on the islands that contain two chemicals deemed damaging to coral reefs."
- US Virgin Islands bans sunscreens containing oxybenzone and octinoxate.
- Miami bans UV chemical sunscreens

SUNSCREEN INGREDIENT BANS

Miami, Florida

On Wednesday, March 13, the Mayor City Commission of the City of Miami Beach will meet on first reading of a ban on the sale of sunscreens containing oxybenzone and octinoxate.

CITY OF MIAMI BEACH, FLORIDA, AMENDING CHAPTER 46 OF THE CODE OF THE CITY OF MIAMI BEACH ENTITLED "ENVIRONMENT", BY CREATING ARTICLE VIII THEREOF TO BE ENTITLED "SALE OF SUNSCREEN PRODUCTS" TO BE PROHIBIT THE SALE OF SUNSCREEN PRODUCTS CONTAINING OXYBENZONE OR OCTINOXATE, OR BOTH AND, PROVIDING FOR REPEALER, SEVERABILITY, CODIFICATION, AND AN EFFECTIVE DATE RECOMMENDATION.

*Reef Safe, Chemical Sunscreen Reduction Proposal
These bans are not applicable to Zinc Oxide Products*

Hawai'i Senate Bill Bans Harmful Sunscreen Chemicals - 9th March 2021

- HONOLULU— Sunscreens containing two harmful petrochemicals, avobenzone and octocrylene, would be banned from sale in Hawai'i under a bill passed today by the Hawai'i Senate. [90]
- The Center has petitioned the U.S. Food and Drug Administration for a national ban on coral-killing chemicals in sunscreens. [90]
- Research demonstrates that octocrylene can disrupt human hormones and have toxic impacts on a variety of aquatic organisms, including corals, fish and marine mammals. A soon-to-be published study shows that octocrylene degrades into benzophenone, a powerful carcinogen, reproductive disruptor and herbicide. [90]

94. <https://www.usatoday.com/story/news/health/2019/05/06/sunscreen-chemicals-absorb-your-bloodstream-fda-study/1123513001/>

25. <https://agupubs.onlinelibrary.wiley.com/doi/full/10.1029/2018GB006034>

90. <https://biologicaldiversity.org/w/news/press-releases/hawaii-senate-bill-bans-harmful-sunscreen-chemicals-2021-03-09/>

Pregnancy and Child Safety

- "Studies reported statistically significant associations between oxybenzone exposure during pregnancy and birth outcomes. One reported shorter pregnancies in women carrying male fetuses; two reported higher birth weights in baby boys; and one found lower birth weights in baby girls (Ghazipura 2017)" [17]
- "Liver and kidney weights were affected after both dermal and oral exposure to BP-3" [18]
- "Oxybenzone detected in nearly every American; found in mother's milk; 1% to 9% skin penetration in lab studies." [17]
- "A pregnant woman who follows the instructions for the recommended-use of sunscreen products containing 6% oxybenzone (two 1-ounce application of sunscreen) could have concentrations of oxybenzone and fetal blood levels reach as high as 3,800 part per billion in the woman, and 384 parts per billion in the fetus. These concentrations of oxybenzone can potentially cause these toxic cellular changes, and give rise to Hirschsprung's Disease." [19]
 - o "Hirschsprung's Disease is a birth defect that develops in the first trimester of pregnancy. Without surgical intervention, obstruction of the bowel may occur, which can give rise to an infancy mortality rate as high as 80%." [19]

Malignant Melanoma (MM) age standardised Incidence rate per 100 000

"Despite use of sunscreens with UV-filters over decades, the incidence of MM (Malignant Melanoma) is still increasing rapidly (Fig. 1) (Handel & Ramagopalan, 2010). Furthermore, an increasing number of experimental animal and in vitro studies indicated that some UV-filters might have adverse effects as endocrine disrupters." [8]

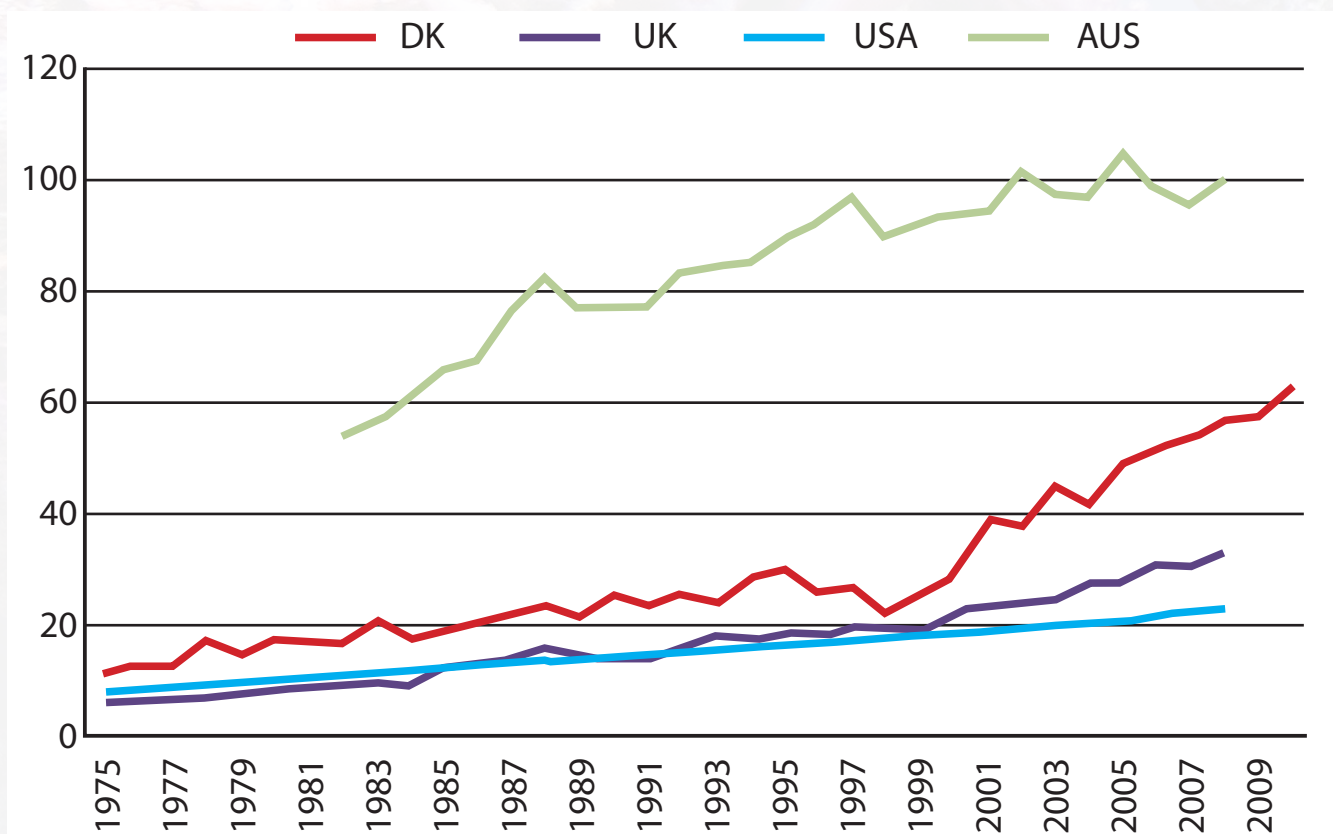


Figure 1

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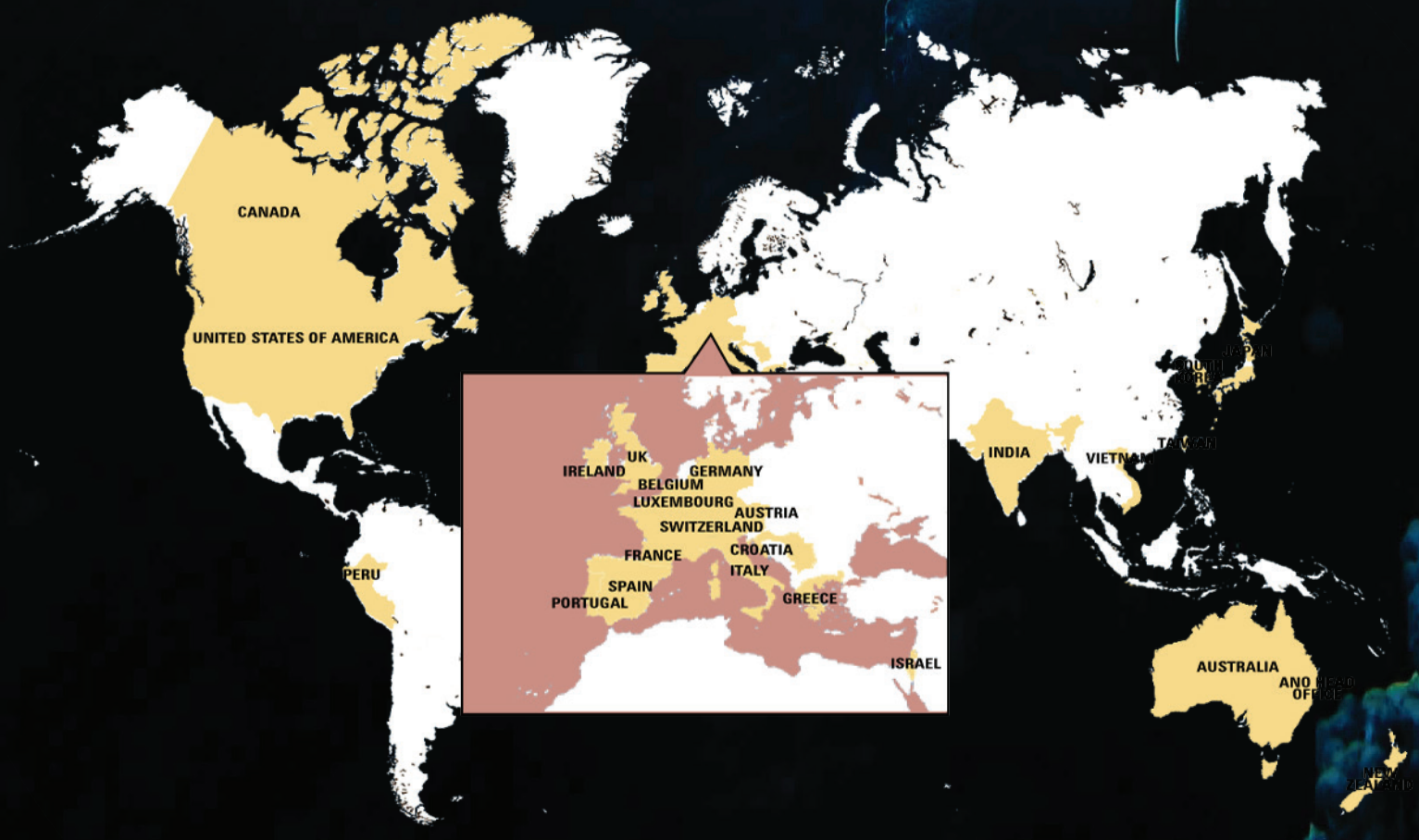
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