

WOMENA SUMMARY AND RECOMMENDATIONS¹

Should we worry? Many people worry that menstrual products may contain harmful substances, particularly since products are used for a prolonged time in close contact with highly absorbent skin around the vagina. So, should we be concerned?

What are the ingredients in menstrual products? Ingredients vary greatly, both by type and brand of product. One common ingredient is cotton, especially used in disposable pads. Conventionally grown cotton has some of the highest levels of pesticide use of any crop. Rayon and polyester, made from wood pulp, are used particularly in tampons and some pads. Plastic is common in tampon applicators, and well as to limit leakage in disposable pads. Most cups are made from medical silicone, with some (cheaper) brands being made from thermoplastic polymers.

Do these ingredients contain substances at harmful levels? Potentially harmful substances include furans and dioxin, glyphosate, and fragrance (which may contain phthalates). Dioxins and glyphosates are considered particularly risky, with at least some authorities ruling them carcinogenic, and recommending zero levels. Dioxin was used in Agent Orange and Roundup; there are numerous suggested health links (cancer, reproductive health problems, allergies and abrasions), but few tests have been done.

Both dioxin and glyphosates are frequently found in pads and tampons, They have not yet been found in menstrual cups. Medical grade silicone does not react to chemicals or absorb bacteria, which may make it a safer option, but one test suggested that recommendations should include boiling before use and cleaning carefully. This review found no study testing reusable pads or cloth..

The question is not only what substances are present, but whether their levels are harmful. Conclusions from recent tests are generally that products such as pads or tampons may contain harmful substances such as dioxin or glyphosates, but at levels considered 'safe'. Cups in general have been tested to have no, or low levels of potentially harmful substances but one test suggests boiling the cup before use.

Are manufacturers required to disclose product ingredients? The short answer is 'no'. Terminologies vary, but many countries classify health care products either as pharmaceuticals or health devices. Menstrual products are usually categorised as 'health devices', meaning they no not need approval before marketing.

What do health authorities conclude? The US Food and Drugs Administration (FDA) recommends that menstrual products should have zero levels of dioxins and pesticide residue, but the guidance is not mandatory, and manufacturers do not always comply. In its resolution of 13 June 2012, the European Parliament called for a Pre-Market Authorisation system for medical devices, as is mandated for pharmaceuticals. Experts suggest choosing unperfumed products with disclosed ingredients, products made from organically grown cotton, or menstrual cups.

Womena commitment: Many questions remain. Two chemicals are considered particularly toxic, occur widely in some brands of tampons and pads: glyphosate and dioxin. WoMena will work with others to advocate for clear and consistent regulations, if feasible also including assessment of products widely used in low-and-middle income countries. **Meanwhile, we understand the evidence to indicate that cups in general are among the safest products, although brand names may differ.**

This is the best evidence we could find. Comments warmly welcome! (please write andisheh.jahangir@womena.dk)

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Introduction

WoMena receives many questions about the use of menstrual cups, from the community we reach out to, from our trainers and from our partners. Therefore, we have created a series titled "WoMena FAQs" where we address these questions and answer them based on the best available scientific literature, consultation with experts, health authority guidelines and manufacturer advice. Please see the end of the document for an explanation of the terms used.

Concerns about harmful substances in menstrual products are common and frequently expressed in alarmist headlines in the media. Sometimes the concerns result in voluntary withdrawal of the product from the market such as one type of tampon by a famous company (Dudley et al., 2018; Rinkunas 2018). WoMena has assessed available evidence to help those who menstruate make informed choices regarding the potentially harmful substances in a number of different products used to absorb or collect menstrual blood. This FAQ is based on a search of peer-reviewed academic literature, manufacturer information and expert opinion. We focus on menstrual products such as tampons, disposable pads, menstrual cups and panty liners. We could find no studies on exposure to harmful ingredients in reusable pads, menstrual underwear or cloth, nor any referring to homemade products. This is an important gap in the data as it omits products which are often used in low- and middle income countries.

What are most menstrual products made of?

Products often have multiple ingredients. Commercial products are often made primarily from cotton or polyester (absorbent material) with additional substances to bind those materials, provide a waterproof barrier, assist with use (e.g. applicator, tampon string) and/or provide fragrance or mitigate odor. Here are a few examples:

Tampons: main ingredients are usually cotton and/or rayon with additional polyester and/or polypropylene components. May have plastic or cardboard applicators.

Disposable pads: main ingredients are usually cellulose, often with plastic to prevent leakage (Woeller et al., 2015). Recent news from Kenya revealed that a major menstrual product manufacturer may have been selling sub-standard products of unknown ingredients under well-known brand names (Gamonde, 2019; Daily Nation, 2019). There is, as yet, no research into the products and ingredients for disposable pads used by small enterprise or cottage industry.In addition to unknown substances in the ingredients, the materials may contain undesirable bacteria.

Menstrual Cups: usually made from medical-grade silicone, with some cheaper cups made from thermoplastic polymers (Kemikalieinspektionen, 2018). Medical grade silicone is hypoallergenic and does not react to chemicals or absorb bacteria, which makes it safe for use in menstrual cups.

Panty liners: often cotton, but with layers made from plastic. Glue used to hold the pad or liner in place may contain allergenic chemicals (Scranton, 2013).

Commercial washable pads: made from cotton and sometimes polyester; main concern would be if not made of certified organic or well-washed cotton could contain residues from dyes, pesticides or various treatments added to fabric. Research is needed as we could find little or no information on reusable pads .

² We leave out other hygiene products such as vaginal douches, although there is evidence that they are associated with health problems, including sexually transmitted infections (Scranton, 2013, Tsai et al 2009).



Washable pads made at home or by cottage industry are often made from cotton or rags, but there is no research into the safety of the materials used .

What potentially harmful substances can be found?

It is beyond the scope of this FAQ to review all safety data of every known harmful substances in menstrual products. Below is an overview of the most common ones.

Glyphosate: Much of the cotton is genetically modified to withstand herbicides which contains glyphosate, a probable carcinogen³;it is found an association between non-Hodgkin lymphoma (NHL) and glyphosate based on the available human evidence (Portier et al., 2016; Zhang et al., 2019).

Dioxins: by-product of cotton and wood pulp bleaching, can be a side product of the chemical process of bleaching ingredients for products. They are highly toxic, an endocrine disruptor, and carcinogen. They also can cause reproductive and developmental problems, and damage the immune system, (WHO, 2016). Bleaching processes have been developed which result in less dioxin.

Phthalates: are common ingredient in fragrances. Menstrual products are often advertised as being 'odour-free', which in turn is an indicator that they contain fragrances (Scranton 2013, Kemikalieinspektionen 2018).

Volatile organic compounds (VOCs): A recent study indicates that surveyed menstrual pads contain VOCs (methylene chloride, toluene, and xylene) which are dangerous to human health. However, amounts measured were below the reference dose (RfD); daily absorption of toluene (VOC) from sanitary pad reached to the maximum of 38.4% RfD (Park et al., 2019). Long-term exposure to various VOCs may cause cancer and damage to the liver, kidneys or central nervous system (NIH, 2019).

What are the potential health risks?

Scranton suggests that dioxins, furans, pesticide residues and unknown fragrance chemicals - found in both disposable pads and tampons - could be associated with cancer, reproductive health problems and/or hormonal disruptions. The vagina is self-cleansing and does not require fragrances or perfumes to clean it. Disposable pads, which contain adhesive chemicals such as methyldibromo glutaronitrile, have also been linked to allergic rashes (Scranton, 2013).

Phthalates used as plasticizer of polymers, chlorine compounds used as bleaching agents in disposable menstrual pads, as well as styrene, endocrine-disrupting chemicals (EDC), chloroform, and chloroethane which were also found in the disposable pads, pose potential health hazards such as breast cancer, infertility, endometriosis for users because they are in prolonged close contact with the skin (WVE, 2014; Bae et al., 2018, Lynn, 2018).

Moreover, studies suggest that chemical workers who have prolonged exposure to carbon disulfide (used in the production of rayon tampons) and rayon in the process of production may experience changes in their menstrual cycles, breast cancer, increased incidence of spontaneous abortion, as well as other negative impacts on their neurologic, cardiovascular, gastrointestinal and immune systems (Hemminki et al.,1980; Zhou et al.,1988; Labrèche et al.,

³ There is as yet no agreement on whether Glyphosate is a harmful substance. It was introduced in 1974, and is the most widely used herbicide worldwide. In March 2015 glyphosate was classified as a probable carcinogen by the International Agency for Research on Cancer, but this was disputed by the EU assessment or the recent joint WHO/FAO evaluation (Tarazona et al., 2017)



2010; Davidson, 2012), and also workers in textile factories due to exposure to synthetic fibres experienced higher risk of miscarriage (Wong et al., 2009).

In addition, due to the byproducts of combustion, menstrual products containing chlorine and polythene pose a health threat to waste collectors working in disposal areas. Disposable pads made of super absorbent polymers (SAP) additionally harm the health of waste collectors and cleaners who have to remove blockages from sewers and clean septic tanks when pads are thrown into toilets (Elledge et al., 2018).

Why are menstrual products different?

Menstrual products come into prolonged contact with genital and vaginal mucous membrane which is highly absorbent. This means that 'Safe levels' of chemicals may be different for menstrual products compared to food. In addition, one woman may use from 5,000 to 15,000 disposable menstrual products during her 35-40 reproductive years (WoMena, 2019). The presence of a potential harmful substance should be assessed not only by its quality, but also the exposure to different population groups (MedTech Europe, 2015).

What is the evidence of harmful substances?

However, little research has been done to investigate the presence of substances with potential negative health consequences in menstrual products at unsafe levels, a recent study indicated disposable pads contained VOCs and phthalates though the amounts measured were different among the brands and were below the reference dose; daily absorption of toluene from disposable pad was of 38.4% reference dose since menstruators are exposed to various chemicals through various routes, consideration should be given to the risks of chemicals that are additionally absorbed from the disposable pad (Park et al., 2019).

In addition, a risk health assessment done by ANSES on the safety of the menstrual products (e.g. tampons, disposable pads, panty liners, and menstrual cups) revealed the presence of various chemical substances in very low concentration and without exceeding the health thresholds; the majority of these substances would come from contamination of raw materials or manufacturing processes (ANSES, 2018). Many of the earlier studies come from the United States and deal with dioxins in tampons, which are the most widely used menstrual product in the US (Scranton 2013).

DeVito and Schecter analysed four brands of tampons and concluded that, although they all contained dioxins, the levels were well below those considered safe for food, and therefore they did not pose a health risk (DeVito and Schecter, 2002). Other researchers arrived at similar conclusions (Scialli, 2001; Archer et al., 2005). The studies did not consider whether levels for foodstuffs are applicable to menstrual products.

Glyphosate has also been studied. For example, a report by the Swedish Chemicals Agency noted that although glyphosate was indeed found in the tampons, the levels were not considered harmful.

The glyphosate analysis was part of a 2018 study of 35 locally available menstrual products - tampons, disposable pads, panty liners and menstrual cups - by the Swedish Chemicals Agency. Tests were done for 62 different potentially dangerous chemicals. The study found 21 chemicals in the products, and there was enough information from other studies and standards to do a risk assessment for 18 of these compounds. Three could not be assessed due to a lack of information on their health effects. One product (a menstrual cup which did not indicate the



country of manufacture but was labelled in Chinese) contained chemicals which could not be assessed with the tests available. The report concluded that the levels of substances were below the levels considered harmful. (Swedish Chemicals Agency, 2018).

It seems that the safety threshold levels were based on the assumption that 100% of the chemical would be absorbed, but any information on whether there should be a multiplier factor related to the number of products used over a menstruator's lifetime could not be found.

In August 2018, the Danish Consumer's Union published a test of seven different menstrual cups. The conclusion was that all the brands of cups were generally free from unwanted chemicals although there was variation by brand in terms of presence of some minor findings of an unwanted phthalate and tar substances (PAHs);all were considered safe to use, and the Consumer's Union concluded that menstrual cups were a good alternative in terms of safety from problematic chemicals. A recommendation was made to boil the cups to ensure removal of any volatile compounds,no reference was made to the manufacturer's printed recommendation to boil the cups (Müller, 2018).

We could find no further information regarding what happens to any harmful substances during disposal of any product (in particular those which are produced in high quantities and incinerated). We discussed environmental concerns in a separate FAQ.⁴

What is being done regarding consumer safety and menstrual products?

Menstrual products are classified as 'medical devices' in the United States, and 'hygiene products' or 'general products' in the European Union. This means manufacturers are not obliged to disclose ingredients or any test results⁵ (Elledge et al., 2018; Kaur, 2018). The US Federal Drug Administration guidance is that tampons should be free of dioxins and pesticide residue, but the recommendation is not mandatory, and testing shows that they do not comply (Scranton, 2013). We have not been able to do a full review of post-marketing surveys (e.g. MAUDE reports in the US) (US.FDA, 2019).

Since 1997, US Congress representative Carolyn Maloney has presented a bill to require testing and disclosure of menstrual product components. None of her proposals has passed. The latest iteration of the bill, presented in 2017, "requires [the National Institute of Health] to study [whether] the contaminants and substances used, such as dioxin, synthetic fibers, fragrances, dyes, and preservatives in feminine hygiene products [which] pose health risks to women who use the products or to the children of women who use the products during or before pregnancy." (H.R. 2379 Robin Danielson Feminine Hygiene Product Safety Act of 2017, 2017; Maloney, 2015). Until more is known, it is recommended choosing unperfumed products which disclose ingredients, products made from organic cotton, or menstrual cups (Mercola, 2013, King, 2017).

Conclusions and recommendations

This topic has many data gaps, party because menstrual product manufacturing companies do not list all the ingredients in their products publicly and they have not been mandated to do so by governments. There are potentially harmful substances in products such as tampons and disposable pads, which this may also be true for other, untested products. Further, chemical exposure safety levels do not currently differentiate between exposure via consumption (as in food) or absorption (as in menstrual products), and neither the length of exposure to menstrual

⁴ WoMena, 2019. FAQ-What is the environmental impact of menstrual products?.

Available from: http://womena.dk/what-is-the-environmental-impact-of-menstrual-products/

⁵ Products such as douches are classified as cosmetics, and are expected to undergo test



products over the reproductive lifespan nor to EDC seem to factor in. We could find no information regarding reusable pads of any material. Menstrual cups made of medical-grade silicone have been tested and found free of harmful substances, but like other products, findings vary by brand.

It is concerning that producers are not required to disclose ingredients or safety evaluations of their menstrual products, and variations in how these products are classified in different countries (e.g. as luxury items, cosmetics, medical devices, hygiene products, general products), complicating consumers' ability to hold manufacturing companies to account.

WoMena is concerned that the standard for the setting levels of harmful substances does not discuss whether exposure levels differ between menstrual products and food.

Womena is also concerned by a lack of research into disposal, whether incineration, burying near water source, landfill, sewers etc. (WoMena, 2019).

Moreover, due to the fact that the high absorption rate of the genitalia for chemicals, and the long-term exposure period demand a thorough investigation on the potential impact of the exposure to VOCs and phthalates (Park et al., 2019).

In order to eliminate or, if not possible, as much as possible reduce the presence of harmful chemical substances, in particular those with carcinogens, mutagens or reprotoxins (CMR), endocrine disruptors or skin sensitisers, it is recommended developing a more restrictive regulatory framework to limit the presence of CMR substances, as well as urging manufacturers to improve the quality of raw materials and revise certain manufacturing processes (ANSES, 2018)

It is suggested that, until better information is available, quality menstrual cup is a safer choice, or unperfumed pads or tampons made from disclosed ingredients and organically grown cotton. WoMena therefore recommends menstrual cups.



Explanation of terms used

Term	Explanation
abrasions	a partial thickness wound caused by damage to the skin
biofilm	a thin but robust layer of mucilage adhering to a solid surface and containing a community of bacteria and other microorganisms
furans and dioxin	short name for a family of toxic substances that all share a similar chemical structure; by-products of converting wood pulp to rayon and chlorine bleaching
glyphosate	an herbicide; in weed killers, used in growing cotton
phthalates	mainly used as plasticizers. For example, substances added to plastics to increase their flexibility, transparency, durability, and longevity
rayon	a manufactured fiber made from regenerated cellulose fiber
tar substances	a general disinfectant
toluene	a colorless, water-insoluble liquid used as a solvent
volatile organic compounds	extremely hazardous organic chemicals that have a high vapor pressure at ordinary room temperature



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