EMERGING LIABILITY RISKS: THE "TOXIC TRIO"

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CHEMICAL DANGERS IN PERSONAL CARE PRODUCTS

Increasing scientific, regulatory, and consumer concerns means increasing risk for manufacturers and suppliers of various personal care products. The potential for synergistic effects of a so-called "toxic trio" of hazardous chemicals used in these products threatens to expose them to latent liabilities. This risk bulletin by **Allianz Global Corporate & Specialty** and **Praedicat**, a leading science-based risk analytics company, reviews possible risk exposures and potential impacts of this trio of chemicals to businesses and the insurance industry.

RISK BULLETIN VOLUME 3, 2018

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EXECUTIVE SUMMARY

The cosmetics industry uses hundreds of chemicals in the manufacturing of its products, dozens of which can be present in the final product, leading to potential consumer exposure.

Among the widely-used chemicals today, three have gained some notoriety, primarily for their use in nail varnish: **dibutyl phthalate (DBP), toluene,** and **formaldehyde** – or the so-called **"toxic trio"** which are prevalent in the personal care industry.

The "toxic trio" has been extensively researched, as they have been used independently for many decades in a wide variety of applications. Each is known to be hazardous: DBP is likely a reproductive system toxin, toluene is a neurotoxin, and formaldehyde is a known carcinogen.

DBP, for example, has approximately a 1% probability of generating greater than $100bn in mass litigation-related losses to the US economy over multiple years. Toluene is so common that its global market volume was $16.6bn in 2016 and projected to increase in the future. The exposure to excessive amounts of formaldehyde among nail salon employees – one study found that 58% of such workers in Salt Lake City, Utah, were so exposed – presents significant potential workplace liability.

Regulators have monitored and controlled these chemicals, and continue to stay abreast of scientific literature. Increased awareness has shifted their attention in recent years toward occupational exposures, particularly in nail and hair salons, although consumer advocates are pushing for increased regulatory attention in consumer applications.

Consumer awareness is growing as the use of cosmetics has increased. Global sales for skin care products alone is anticipated to grow by 40% to $180bn by 2024. In response to increased consumer awareness of toxic chemicals in daily-use products, manufacturers have begun to remove some of these three chemicals from their products to avoid exposure to significant latent liabilities.

Significant latent liability could arise in the future due to the confluence of increasing consumer exposure with the potential discovery of bodily injuries linked to "toxic trio" exposure. Should science validate the hypothesis that "toxic trio" exposure causes bodily injury, the resulting possible loss scenarios are manifold.

The risk of forced product recalls is especially pertinent. There is a possibility, for example, that a regulatory body could determine that a product containing one of the "toxic three" chemicals was either hazardous or risky to consumers. Manufacturers would have to recall all the implicated products and then consumers could file lawsuits accordingly, alleging fraudulent marketing and related claims, including medical monitoring.

Manufacturers who market and label their products as being "three-free" or variations on that theme could open themselves up to additional liability if their products, in fact, contain the stated chemicals. This may be true even if the offending chemicals were contaminants in materials purchased from upstream vendors. A testing regime needs to be implemented that ensures the reduction of the risk of mislabeling.

Companies should proactively monitor scientific literature to find leading indicators of risk rather than reacting to public perception or regulatory actions.

Furthermore, these scenarios and others can be addressed by insurance solutions such as general liability policies for manufacturers or suppliers.

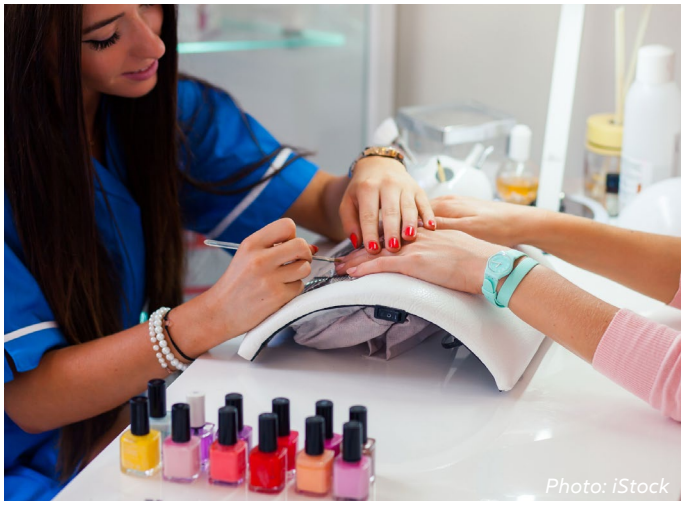
WHAT IS THE "TOXIC TRIO"?

In recent years, nail varnish has become notorious for the potential co-occurrence of three chemicals that have been dubbed the "toxic trio": **dibutyl phthalate (DBP), toluene,** and **formaldehyde**. The "toxic trio" chemicals are also used in body lotions, adhesives, hygiene products, fragrances, and other personal care products that are frequently used by people of all ages. In fact, children and teenagers are using ever-growing numbers of cosmetics products on a regular basis, and any of these products may contain "toxic trio" chemicals. Because of the presence of one or more members of this trio combined with the increased exposure to cosmetics in all segments of the population, the chemical composition of a wide array of cosmetic products has come under increased scrutiny.

Increasing numbers of products that may contain one or more of the "toxic trio" are used regularly

The constituents of the toxic trio are all common chemicals, used in a wide array of industries and processes, and are present in hundreds of different types of products. Interestingly, the term "toxic trio" is not generally used to reference these three chemicals outside of nail varnish and related applications, despite the many ways they can co-occur in consumer products.
The name derives from the fact that each of these chemicals has known toxic properties, ranging from promoting the formation of cancers (carcinogenicity) to eye damage, neurological injuries, and even birth defects. This report breaks down the three components of the "toxic trio", summarizes their health effects, explores the ways workers and consumers could be exposed, and discusses some of the risks companies need to consider.

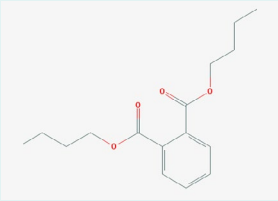
Research to understand the synergistic effects of the "toxic trio" is in its infancy



The "toxic trio" could affect workers and consumers alike and could expose companies to latent liability risks

1 DIBUTYL PHTHALATE

Di-n-butyl phthalate*



CAS Number: 84-74-2
EC Number: 201-557-4
Molecular formula: $C_{16}H_{22}O_4$
Molecular weight: 278.35 g/mol

Source: PubChem *Chemical name

DBP is a ubiquitously used member of the family of short-chain phthalate chemicals. It is mainly used to soften plastics and other polymers, including neoprene, polyvinyl acetate, nitrile rubber, and nitrocellulose. It is also used as an additive in adhesives, printing inks, insecticides, lacquers, textiles, and even rocket fuel. Furthermore, DBP is a component of enteric coatings for medications to prevent their dissolution or disintegration in the gastric environment. Although not permitted in the European Union since the release of directive 20114/93/EC in 2015, DBP may be present in perfumes, body lotions, and all kinds of personal care products in the US, which threatens to meaningfully expose consumers. The exposure to DBP is so broad that Praedicat's models suggest it has the potential to exceed approximately $100bn in mass litigation-related losses to the US economy, over multiple years, at a 1% probability.

When used as a plasticizer, DBP is rarely chemically integrated into the polymers themselves; instead, it is added to the bulk material to make a mixture. This results in DBP (and other phthalates, for that matter) being able to easily migrate out of the plastic and into the surrounding environment. When DBP is used in cosmetics it has the same property: **high mobility.** As a result, body lotions, perfumes, and nail varnishes containing DBP, because they are applied directly to the skin, have a clear dermal exposure route that theoretically allows DBP to enter the bloodstream, although until recently it was unclear whether it actually did so. Three separate peer-reviewed studies in the last decade have shown that it does [Janjua, N.R. 2008; Pan, T.L. 2014; Sugino, M. 2017]. Collectively, this research demonstrates that DBP can cross the skin but that the transport rate is likely to depend on the activity of certain enzymes that start the process of metabolizing DBP into its breakdown products.

Once DBP is in the body, the peer-reviewed scientific literature has investigated its link to three categories of potential bodily injury: **endocrine system (glands and hormones) injury/endocrine disruption, reproductive injury,** and **developmental injury due to prenatal exposure**.

DBP potentially could exceed $100bn in mass litigation-related losses to the US economy, over multiple years, at a 1% probability

All three "toxic trio" chemicals carry the potential for reproductive injury

The table below shows the output of Praedicat's proprietary model that evaluates the scientific consensus regarding hypotheses of bodily injury. To derive these estimates, Praedicat extracts metadata describing the methodology and results of each peer-reviewed scientific article addressing the hypothesis connecting a chemical to a bodily injury. These article-level metadata are then aggregated to generate an overall score of scientific consensus and to project its evolution into the future.

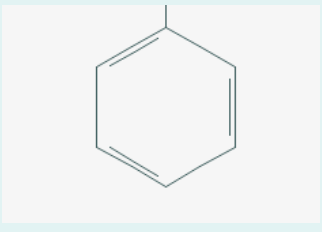
DBP'S POTENTIAL TO CAUSE BODILY INJURY AND ITS PROJECTED EVOLUTION*

Bodily Injury Category	Scientific Consensus	Projected Change
Developmental injury	Medium	Flat
Endocrine disruption	Medium	Large increase
Reproductive injury	Medium-high	Small increase

** according to Praedicat's model of consensus of the peer-reviewed scientific literature*

2 TOLUENE

Toluene



CAS Number: 108-88-3
EC Number: 203-625-9
Molecular formula: C_7H_8
Molecular weight: 92.14 g/mol

Source: PubChem

Toluene, also called methylbenzene, is one of the simpler members of the class of chemicals known as aromatic hydrocarbons. It is found in fossil fuels and is also a by-product of the oil refining process. Furthermore, toluene is produced by burning many kinds of organic fuel and is generally present in this type of emission.

Industrially, toluene is a basic building block chemical used in the production of other chemicals, polymers, and pharmaceuticals. Toluene is also a solvent commonly found in paints, inks, adhesives, paint thinner, stain removers, fragrances, hand and nail care products, and a wide variety of personal care products. The value of the toluene market was $16.6bn in 2016 and significant growth is projected over the coming years.

As an oft-used product component, toluene had a market value of over $16bn in 2016

The wide-ranging use of toluene as a solvent in the personal care product applications listed above presents two potential exposure routes: **dermal** and **inhalation**. Dermal exposure results in slow absorption of toluene into the bloodstream, but toluene's presence in body lotions and other cosmetics means that it has enough time to be absorbed when applied dermally. Because toluene easily evaporates and is often used for that property, its presence in air is nearly assured during the application and drying of products containing this chemical. One study found that half of Korean nail salon workers were exposed to more toluene than permitted.

With exposure to toluene common from solvent-containing products, including personal care products, the potential for bodily injury is important to understand. Scientists have studied toluene fairly extensively, publishing 180 studies investigating its ability to cause bodily injury. As before, in the adjacent table we summarizes the consensus and projected evolution of the peer-reviewed scientific literature using Praedicat's models.

TOLUENE'S POTENTIAL TO CAUSE BODILY INJURY AND ITS PROJECTED EVOLUTION*

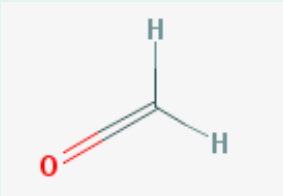
Bodily Injury Category	Scientific Consensus	Projected Change
Developmental injury	Medium-high	Flat
Ear injury	Medium-high	Flat
Eye injury	Medium	Flat
Nervous system injury	High	Small increase
Reproductive injury	Medium-low	Flat

** according to Praedicat's model of consensus of the peer-reviewed scientific literature*

Most personal care beauty products contain one or more of the "toxic trio" of chemicals

3 FORMALDEHYDE

Formaldehyde



CAS Number: 50-00-0
EC Number: 200-001-8
Molecular formula: CH_2O
Molecular weight: 30.03 g/mol
Source: PubChem

Source: PubChem

Formaldehyde is the simplest member of the aldehyde chemical class and is a volatile organic compound. Formaldehyde is listed as a known carcinogen by the US National Toxicology Program and the International Agency for Research on Cancer (IARC). The most widely-known use of formaldehyde is as the main constituent of formalin, used for preserving biological specimens and embalming. However, formaldehyde is most commonly used to make resins – precursors to many plastic and adhesive chemicals – that are used in dozens of industrial processes that eventually produce hundreds of consumer products: pressed wood, disinfectants, clothing, adhesives, laminates, insulation, paper products, and personal care products. Formaldehyde is often a component of hair straighteners used both in salons and at home.

Unlike DBP and toluene, formaldehyde has been the subject of product liability lawsuits. Formaldehyde-containing resins and adhesives in pressed wood products led to a series of lawsuits, starting in 2013, alleging that Lumber Liquidators, Inc. sold wood laminate flooring products in the US and Canada that emitted significantly more formaldehyde than allowed. The company has paid tens of millions of dollars to settle these claims, which (notably) have been about issues other than bodily injury.

Unlike DBP and toluene, formaldehyde has been the subject of product liability lawsuits

As with DBP, formaldehyde's use in nail products has attracted research attention on exposure levels and worker safety. A 2013 study found that 58% of workers in nail salons in and around Salt Lake City, Utah were exposed to excessive amounts of formaldehyde.

Formalin, a solution of formaldehyde in water, is used for preserving biological specimens and embalming

Formaldehyde's well-known properties as an irritant and toxicant have led to news stories discussing the possible effects. In particular, the fact that formaldehyde is the main constituent of formalin is often used to frame the issue. Using Praedicat's model to evaluate the current consensus and projected evolution of the peer-reviewed scientific literature, we summarize the hypothesised bodily injuries linked to formaldehyde exposure in the table.

FORMALDEHYDE'S POTENTIAL TO CAUSE BODILY INJURY AND ITS PROJECTED EVOLUTION*

Bodily Injury Category	Scientific Consensus	Projected Change
Blood cancer	Medium-high	Medium increase
Cognitive disorder	Medium	Medium
Ear, nose, or throat tumor	High	Flat
Lung cancer	Low	Flat
Lung injury	High	Flat
Nervous system injury	Medium	Large increase
Reproductive injury	Medium-high	Medium increase

** according to Praedicat's model of consensus of the peer-reviewed scientific literature*

Worker exposure to the "toxic trio" in nail salons has attracted much regulatory attention

CO-EXPOSURE: DOES IT MATTER?

A significant reason the "toxic trio" has received traction in scientific literature and the media is the fact that nail varnishes and hardeners can expose consumers to all three chemicals at the same time. Not all co-exposures, however, are created equal. Some co-exposures of otherwise non-toxic substances can increase the toxicity of a known toxin; for example, combining silica and lead compounds can enhance cellular toxicity. Similarly, co-exposure to benzene and formaldehyde may increase the risk of leukemia beyond that expected from either chemical alone – a synergistic effect. In other cases, the net effect of co-exposure is no different than the sum of the individual exposures – an additive effect. Finally, some co-exposures result in less toxicity than the individual compounds – a protective effect. In most cases a mechanistic understanding of the toxicology of the individual chemicals can aid in understanding which co-exposure result may manifest.

Thus far, scientists have not directly studied the toxic effects of co-exposure to all three members of the "toxic trio", either theoretically or due to exposure from personal care products. They have only investigated the presence of these three chemicals as allergens, and only in the context of nail products. Studies investigating the potential effects of exposure to any of the pairings of DBP with either toluene or formaldehyde are also sparse and focus primarily on potential exposure routes rather than toxicology. Due to the ubiquity of both toluene and formaldehyde in industrial processes and consumer products, several hundred publications study both chemicals. Much of this research has focused on indoor air pollution and short-term upper respiratory effects, but rarely use an experimental design able to distinguish between the different co-exposure effect types described above. Outdoor pollution research often mentions both of these atmospheric contaminants and investigates a variety of long-term effects, but also rarely provides the information to establish how combined exposures differ from individual exposures.

The scientific community continues to focus more on co-exposures and potential synergistic effects. One could reasonably expect the first co-exposure studies that can provide information about all three members of the "toxic trio" to focus on **reproductive injury** – that is the only harm category that is already being actively studied for all three. Most chemicals with active hypotheses in this area focus on spontaneous abortion or infertility; currently formaldehyde is linked to the former while DBP and toluene are linked to the latter. As data accumulates that illuminate the underlying mechanisms by which DBP, toluene, and formaldehyde cause bodily injury we can also expect new insights to lead in directions not yet considered and find new ways in which these chemicals can affect each other's toxicological properties.

REGULATION

Toluene, formaldehyde, and DBP all have long regulatory histories. In fact, all three were subject to one of the first rounds of establishing **Permissible Exposure Limits (PELs)** by the US Occupational Safety and Health Administration (OSHA) in 1970. At that time, the PEL was established at 5 mg/m^3 for DBP, 2 mg/m^3 for toluene, and 0.75 parts per million for formaldehyde (approximately 0.92 mg/m^3). Regulations and determinations from quasi-regulatory bodies such as IARC have followed suit, yielding a long history of these determinations.

All these prior determinations, however, have been focused on each chemical individually. It was not until further recognition of the potential effects of these chemicals that regulators began to look at them collectively. One of the earlier efforts grew out of the California Healthy Nail Salon Collaborative, started in 2005, to help address the rise of health issues in salon workers. While their efforts at the state level took until 2016 to bear fruit with the passage of California State Assembly Bill 2125, the City of San Francisco adopted a regulation in November 2010 to recognize some salons as **"Healthy Nail Salons"** based on, among other things, eliminating the use of DBP, toluene, and formaldehyde. Several other cities and counties in California and around the US have followed suit.

At the US federal level, OSHA has also recognized the need to disseminate information regarding exposure to DBP, toluene, and formaldehyde. While no regulations specific to nail salons and the "toxic trio" have been promulgated, OSHA reinforces the potential mitigation measures that salons should use to reduce exposures to DBP, formaldehyde, toluene, and several other chemicals. The US Environmental Protection Agency (EPA) published a document in 2007 describing best practices for protecting the health of nail salon workers. While focused on this single exposure setting, the risks of exposure to these products from personal care products demands similar attention and vigilance. All regulatory and consumer-focused agencies recommend choosing products with lower concentrations of potential toxins and eliminating them whenever possible.

> The most severe adverse effects of the "toxic trio" can have long latency periods of many years

As data on chemical exposures from personal care products mount, one might expect regulators to turn their attention beyond workers and expand their scope toward consumers. Personal care products, including nail varnish, body lotion, and others, are used by children, teenagers, and adults on a near-continuous basis. Furthermore, the most severe adverse health effects of these products can have long latency periods and might not become clear for many years.

Awareness of the occupational hazards is leading to increased awareness of the need for regulations, although thus far it has been on a voluntary basis. As further

evidence accumulates and epidemiological studies get published, some of these voluntary standards may transition to regulations if the risks are deemed to be sufficiently large.

"THREE-FREE": MANUFACTURERS RESPONSE

The "toxic trio" public outcry and increasing awareness of exposure to these chemicals by nail salon customers and workers on a regular basis have led some manufacturers to create and market their products as being **"three-free": nail products without DBP, toluene, or formaldehyde**. In fact, cosmetic companies have seized on the "chemical-free" trend and are even advertising their cosmetics as "five-", "seven-" and "nine-free" (see box). The confluence of the San Francisco Safer Salons program and advertising of nail products to be "three-free" led the California Environmental Protection Agency (CalEPA) to assess the veracity of the claims, and it published a report with its findings in 2012.

WHAT ARE FIVE-, SEVEN- AND NINE-FREE PRODUCTS?

"FIVE-FREE"	"SEVEN-FREE"	"NINE-FREE"
No DBP, toluene, formaldehyde, formaldehyde resin or camphor	No DBP, toluene, formaldehyde, formaldehyde resin, camphor, ethyl tosylamide or xylene	No DBP, toluene, formaldehyde, formaldehyde resin, camphor, ethyl tosylamide, xylene, parabens or acetone

The CalEPA investigation tested 25 nail products to determine whether they contained members of the "toxic trio" and if those findings were consistent with the marketing claims on the products' labels. None of the 25 samples contained enough formaldehyde to be detected. However, of the 12 products claiming to be free of one or more members of the "toxic trio", only two of them truly were "three-free". Furthermore, of the products claiming to be toluene-free, only those same two products truly were. Four products contained DBP, but only one of those claimed to be DBP-free. Interestingly, more products not making claims to be free of toluene actually were toluene-free (five of 13).

In general, products not making claims related to the "toxic trio" were freer of these ingredients than those products that did make such claims. The accuracy of "five-", "seven-" and "nine-free" marketing claims have not been validated.

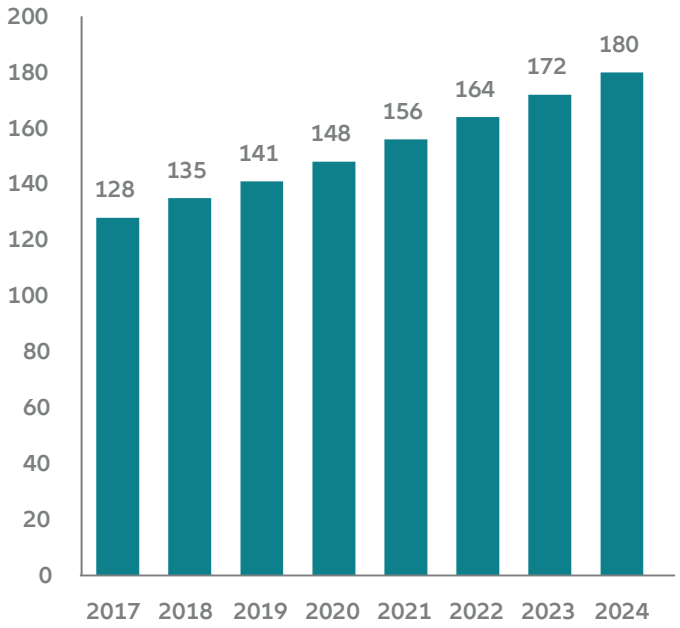
This powerful example indicates manufacturers need to more tightly control their production processes and labelling. The findings of the CalEPA report could fuel additional science to understand risk, which has already begun, but could also lead to lawsuits for false marketing claims, although there are no known cases claiming such. One research group published a study using the results of the CalEPA report to assess the risks to nail salon workers, salon patrons, and home users of nail products. Using their "highly conservative assumptions", all three categories of nail product users could be exposed to DBP or toluene at levels exceeding regulatory limits.

Some manufacturers have been substituting the "toxic trio" chemicals out of their products, but the functions they serve are integral to the product. DBP, for example, provides plasticity and flexibility to the final product. Because removing DBP can increase the product's brittleness, manufacturers have turned to other plasticizers, often triphenyl phosphate, which is also used as a flame retardant. This opens manufacturers up to the possibility of substituting chemicals known to be dangerous with chemicals that may turn out to be as bad or worse – so-called **regrettable substitution**.

The CalEPA report also highlighted a set of 26 other chemicals that are either plasticizers, solvents, or volatile organic compounds that were detected in their nail product samples. This leads to the assumption that other personal care products, which have not yet been investigated, make claims of being free from chemicals that a thorough analysis would not substantiate. This includes specific make-up product lines marketed specifically to children and teenagers.

Nail varnish, body lotion and other personal care products are used regularly by children, teenagers, and adults

PROJECTED SIZE OF THE GLOBAL SKIN CARE MARKET FROM 2017 TO 2024 (IN BN USD)



Source: Statistica.com https://www.statista.com/statistics/254612/global-skin-care-market-size/

RISK CHALLENGES

In the past, the profile of consumers using cosmetics was stable and well-defined. More recently, this consumer group has expanded and significantly more products have become available and been actively marketed to children and teenagers. This has brought market penetration to heights not seen before in many of the various product segments, be it skin care, fragrances, hair care, oral care, bath and shower, or others.

The world turnover (global sales) for skin care products, representing the biggest segment of personal care products, is anticipated to grow by 40% to $180bn by 2024 .

This results in a compounded multi-factor increase in potential liability exposures – increased market size leads to increased risk of the discovery of new adverse effects from cosmetics while simultaneously increasing the number of people who may potentially suffer the newly discovered adverse effects.

Skin care products, alone, are anticipated to grow by 40% to $180bn by 2024

Increased regulation, however, can be a counterbalancing force that reduces consumer exposure over time. For example, German regulators have banned DBP completely from use in baby products, personal health care products, and toys. Toluene and formaldehyde can be used in limited quantities, only in specified products. Regulators consistently use new scientific findings to guide their prioritization to reduce exposure to potentially harmful ingredients. Having a window into the potential future path of scientific knowledge via Praedicat's analytics gives a glimpse into the likelihood that regulatory action could be taken, increasing predictability for both cosmetic manufacturers and their insurers.

Furthermore, consumers, manufacturers, and regulators recognize that beauty and personal care products are lifestyle products. This minimizes the tolerance of adverse effects and health risks from using these products because the risk/benefit analysis rests on little measurable benefit to the user. In comparison, consumers accept significantly more risk when using drugs or other life-saving products because the benefits significantly outweigh the risks.

Consumers have grown increasingly aware of the risks posed by cosmetics ingredients and expect manufacturers to avoid using potentially hazardous ingredients. Manufacturers should be aware of consumer perception and diligently monitor their products for contamination. Failure of any of these pillars of risk management increases the risk to a manufacturer's reputation and bottom line .

As the CalEPA investigation showed, there is the additional risk of inaccurate labelling. Products that are labelled "three-free" yet still contain one or more of these substances significantly increase both liability exposure and reputational risk for the producer.

To a consumer it will not matter whether the presence of DBP, toluene, or formaldehyde was caused by the manufacturer of the beauty product itself, intentionally or otherwise, or if it was the fault of one of the suppliers. The number of lawsuits alleging false labelling or misleading marketing is exceptionally high in the US. Therefore, the producing company is urged to maintain stringent risk management procedures in relation to its suppliers.

POSSIBLE INSURANCE SCENARIOS

Because of the known toxicity of the constituents of the "toxic trio" combined with the possibility of future scientific findings strongly linking adverse outcomes to the trio's use in cosmetics – be it separately or combined – several loss scenarios present themselves. These events may be covered in existing insurance solutions with insurers such as AGCS, be it on an indemnity basis or only on a defense cost basis. These scenarios may comprise one or more of the events outlined below.

1. **Known and intended inclusion of one or more "toxic trio" chemicals in personal care products**
   - The manufacturer of the products and/or its suppliers may be targeted in litigation alleging bodily injury due to the products' composition. The manufacturers cannot disclaim liability due to their knowledge of the chemicals' incorporation into their products.
   - Juries may not award damages, but the cost of defending against the allegations accumulates. General liability insurance policies may respond to claims for these costs.
2. **Unknown existence of one or more "toxic trio" chemicals in personal care products where no marketing claim was made regarding their presence or absence**
   - The manufacturer of the products and/or its supplier may be targeted in litigation alleging bodily injury due to the products' composition. Manufacturers may be able to limit their liability because the presence of the chemicals was unintended and they may be able to pin the responsibility on their upstream suppliers. Upstream suppliers may be found liable for not indicating the presence of potentially hazardous chemicals in their products.
   - Manufacturers may file suit against their suppliers for similar reasons.
   - Juries may apportion responsibility to the manufacturer and/or its upstream suppliers, triggering indemnity payments. Both the manufacturer and its suppliers must pay defense costs. General liability insurance policies may cover these costs.
3. **Unknown existence of one or more "toxic trio" chemicals in personal care products where marketing claims represented that the products were "three-free" or the equivalent**
   - As with the first two scenarios, the manufacturer and its suppliers may be targeted in litigation alleging bodily injury due to the products' composition. The allegations may also include claims of fraudulent marketing due to the disproven claims of the products being "three-free".
   - Manufacturers may file suit against their suppliers for similar reasons.
   - Juries may find in favor of the plaintiffs and award damages based on one or more of the allegations. They may additionally apportion responsibility to the manufacturer and/or the suppliers. In any case, both must pay significant defense costs. General liability insurance policies may offer coverage for these claims.
4. **Product recalls are mandated by regulatory agencies due to research findings indicating that a product is either hazardous or risky**
   - Manufacturers must recall all the implicated products. Consumers may file lawsuits alleging fraudulent marketing and related claims, including medical monitoring.
   - The product recall would give rise to direct or third-party costs that may be covered under separate consumer product recall or contaminated products policies or as part of the general liability policies of both the manufacturer and its suppliers.
   - If lawsuits are filed, juries may award damages, including requiring the manufacturer and/or supplier to provide medical monitoring to exposed individuals. General liability policies may cover these claims. Some suppliers may need to indemnify the manufacturer for their responsibility in introducing the chemical.
   - Companies will suffer loss of revenue from recalls, product discontinuation, and potentially from a decline in brand reputation that would also require significant investment in brand rehabilitation costs.

If any of the "toxic trio" appear in a product, the manufacturer may be targeted in litigation if it has claimed the product is "three-free"

CONCLUSION

The "toxic trio" of DBP, formaldehyde, and toluene may be present in a variety of personal care products and subsets of the trio are often present in a wide array of consumer goods. The scientific evidence is clear that DBP, toluene, and formaldehyde have at least some toxic properties. Studies have investigated the toxicity of each single ingredient, but it is currently unknown whether co-exposure to these chemicals can have a synergistic toxic effect on human health in the short, medium, or long-term. Nonetheless, research has started to characterize both the exposure and potential synergistic effects of the "toxic trio".

While the current literature has focused on the "toxic trio" in nail varnish, research is likely to emerge studying other personal care products. The continued growth of the consumer market for cosmetics and in the number of salons professionally applying cosmetics points to an increasing number of both worker and consumer exposures to these chemicals. Increased exposure, in turn, enhances the ability of scientists to ascertain whether they cause latent bodily injury and presents increased opportunity for high-cost loss scenarios to come to pass. Closely monitoring the evolution of the scientific literature and acting on the development with adequate product design and labelling is the best way to stay abreast of and reduce the potential risk from using these chemicals or products containing them.

Toxicity and the potential liabilities for causing bodily injury are but one of the potential consequences of making products with these chemicals. Manufacturers who market and label their products as being "three-free" or variations on that theme could open themselves up to additional liability if their products, in fact, contain the stated chemicals. This may be true even if the offending chemicals were contaminants in materials purchased from upstream vendors. A testing regime needs to be implemented that ensures the reduction of the risk of mislabelling.

AGCS partners with innovative companies in ways that yield actionable information about a company's exposure to "toxic trio" chemicals and how they can transparently manage the risks associated with chemicals in cosmetics. By leveraging science-based business intelligence from Praedicat, AGCS helps its clients make more informed decisions about the chemicals, products, substances, and processes involved in their business.

The growth of the consumer cosmetic market and the number of professional salons means more worker and consumer exposures

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FURTHER INFORMATION

Allianz and Praedicat are partnering to advance product stewardship and risk management with forward looking science-based analytics. Evaluating the current state of scientific knowledge about these risks and its projected evolution is useful both to companies and their insurers. This enables both qualitative and quantitative assessments of latency risk that provide the necessary information to implement risk management strategies, including provisioning appropriate insurance coverage. Risk Managers can use this information to look around the corner and mitigate risk before it could ever manifest as a liability by making appropriate chemical substitutions in their products early in the scientific discovery process, thereby preserving future revenue and brand reputation.

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