11-2019

Adhesive removers in the ICN: Summary

Children's Mercy Kansas City

Specific Care Question

For patients in the intensive care nursery (ICN) who require devices that are secured by an adhesive, have harms been reported for the adhesive remover ADAPT made by Hollister, or the barrier film Cavilon™ No Sting Barrier Film 3342 made by 3M?

Recommendations Based on Best Evidence Only

A recommendation for or against the use of either product (a) Hollister ADAPT Universal Remover Wipe or (b) 3M Cavilon™ No Sting Barrier Film cannot be made. Literature evidence was not found to answer this question. However, the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) guideline (Brandon et al., 2018) recommends the use of silicone-based barrier films and adhesive removers when appropriate. Both ADAPT and Cavilon™ are silicone-based products. The guideline does not define "when appropriate". An extensive search on the main ingredient, hexmethyldisiloxane, a silicone compound that is the active ingredient in both products did not yield research that addressed this question. When there is a lack of scientific evidence, standard work should be developed, implemented, and monitored.

Literature Summary

Background. The ICN at Children's Mercy Kansas City uses the Medi-Sol Adhesive Remover for Skin by Orange Sol Medical. Medi-Sol is an oil-based product, and skin should be washed to remove the product from skin after use. A request was made to the ICN to consider an alternative adhesive remover and a barrier film, ADAPT Universal Remover Wipe by Hollister, and Cavilon™ No Sting Barrier Film 3342 made by 3M. (These alternative products are silicone based, and the active component is hexamethyldisiloxane. The summary of the toxicology report from Union Carbide (Myers & Ballantyna, 1982) is found in Table 1. It reports Lethal Dose 50 (LD50) and Lethal Time 50 (LT50) in terms of hexamethyldisiloxane applied in ml/kg/doses. The dose amount of hexamethyldisiloxane for ADAPT or Cavilon™ is not reported in ml/kg, rather it is reported as "percent by product weight" (See Table 2). Information from Material Safety Data Sheets is summarized in Table 3.

Study characteristics. The search for suitable studies was completed on August 5, 2019. N. Allen, MS, MLS, RD, LD, CPHQ reviewed the results and removed studies in adults and those only regarding ostomy care. B. Haney, RNC-NIC, MSN, CPNP-AC, FELSO reviewed the remaining 58 titles and/or abstracts found in the search and identified one guideline and 33 single studies believed to answer the question[a]. The identified guideline (Brandon et al., 2018) is from AWHONN and it makes specific recommendations on silicone adhesive removers and is included in this document. After an in-depth review of the remaining articles, no additional studies answered the question.

Have harms been reported for the adhesive removers ADAPT or Cavilon™ No Sting Barrier Film? When addressing skin care in the hospitalized neonatal population factors such as adhesive-related skin breakdown, transdermal absorption of toxins, and potential allergen sensitization must be considered (Johnson, 2016). No studies were identified that evaluated either product. However, both products are silicone-based products.

The AWHONN guideline (Brandon et al., 2018) used the framework from the American Nurses Association Manual to Develop Guidelines (Marek, 1995) The methods employed to write the guideline were not reported in the guideline. Therefore, the AGREE II[b] could not be employed to determine the appropriateness to adopt the guideline as the governing guideline for this CAT.

Identification of Studies

Search Strategy and Results (see Figure 1)

EMBASE
Search 1
#1 'hexamethyldisiloxane'/exp OR 'hexamethyldisiloxane':ti,ab
#2 #1 AND ('skin'/exp OR skin:ti,ab OR dermis:ti,ab OR epidermis:ti,ab) AND English:la YIELD: 3
One abstract selected: Cressey & Scheinman, 2012 -> searched for similar records (100) One article selected: Cressey, Belum, et al. 2016.

#1 'hexamethyldisiloxane'/exp OR 'hexamethyldisiloxane':ti,ab AND English:la
#2 #1 NOT ('animal experiment'/exp OR 'model'/exp OR 'in vitro study'/exp OR 'nonhuman'/de) YIELD: 185

Search 2
#1 'emollient agent'/exp OR cavilon:ti,ab OR 'no sting':ti,ab OR 'brava adhesive remover':ti,ab OR 'adapt no sting':ti,ab OR "sensi-care':ti,ab OR 'skinsafe':ti,ab OR 'pelican protect':ti,ab OR 'ostoguard':ti,ab OR 'appeel':ti,ab OR 'lift plus':ti,ab
#2 'hexamethyldisiloxane'/exp OR 'hexamethyldisiloxane':ti,ab OR silicone*:ti,ab
#3 'skin injury'/exp OR 'dermatitis'/exp OR 'drug eruption'/exp OR 'skin discomfort'/exp OR 'skin fragility'/exp OR 'skin irritation'/exp OR 'skin manifestation'/exp OR 'skin pain'/exp OR 'erythema'/exp
#4 #1 AND #2 AND #3 AND English:la NOT ('animal experiment'/exp OR 'model'/exp OR 'in vitro study'/exp OR 'nonhuman'/de OR porcine:ti,ab OR rabbit:ti,ab OR mice:ti,ab OR rats:ti,ab) YIELD: 16

PubMed

Search 1
(hexamethyldisiloxane[nm] OR hexamethyldisiloxane[tiab]) AND (skin[tiab] OR dermatitis[tiab]) YIELD: 0

Search 2
(hexamethyldisiloxane[nm] OR hexamethyldisiloxane[tiab]) AND (ostomy[tiab] OR stoma[tiab] OR adhesive*[tiab] OR remov*[tiab]) Yield 19l

Search 3
(hexamethyldisiloxane[nm] OR hexamethyldisiloxane[tiab] OR silicone*[ti] OR cavilon[tiab] OR "no sting"[tiab] OR "brava adhesive remover"[tiab] OR "adapt no sting"[tiab] OR "sensi-care"[tiab] OR skinsafe[tiab] OR "pelican protect"[tiab] OR ostoguard[tiab] OR appeel[tiab] OR "lift plus"[tiab]) AND (skin[tiab]) AND (dermatitis[mh] OR dermatitis[tiab] OR "skin injury"[tiab] OR "skin injuries"[tiab] OR stripping[tiab] OR "skin tear"[tiab] OR "tension injury"[tiab] OR blister[tiab] OR maceration[tiab] OR folliculitis[tiab]) AND English[la] NOT (animals[mh] NOT humans[mh]) NOT (eye[tiab] OR eyelid[tiab] OR retinal[tiab] OR implant*[tiab] OR conjunct*[tiab] OR lenses[tiab] OR subconjunct* OR porcine[tiab] OR rabbit[tiab] OR mice[tiab] OR rats[tiab]) YIELD 42

Scopus
TITLE-ABS-KEY(hexamethyldisiloxane) AND TITLE-ABS-KEY(skin OR dermatitis OR {skin injury} OR {skin injuries} OR {skin stripping} OR {skin tear} OR {skin pain} OR erythema OR {skin irritation} OR {fragile skin} OR {skin damage} OR {skin maceration} OR {drug eruption} OR {skin discomfort}) YIELD: 6

Records identified through database searching *n* =271
Additional records identified through other sources *n* = 3

Studies Included in this Review

Citation	Study Type
Brandon et al. (2018)	AWHONN Guideline

Studies Not Included in this Review with Exclusion Rationale

Citation	Reason for exclusion
Amer, Diab, Soliman, and Amer (2017)	Addresses cleansers, not adhesive removers
Benbow (2011)	Skin of the elderly, not neonatal
Bernatchez, Mengistu, Ekholm, Sanghi, and Theiss (2015)	Coefficient of friction measured on the palmar surface of adult hands
Berry, Black, Smith, and Stuchfield (2007)	Survey of WOC nurses' knowledge of specific products

Black (2007)	Overview of products from the United Kingdom
Boswell and Waker (2016)	Used silicone adhesive removers, did not evaluate them
D. H. Brandon, Coe, Hudson-Barr, Oliver, and Landerman (2010)	Does not answer the question, evaluates skin condition using the Neonatal Skin Condition Score (NSCS) and trans-epidermal water loss (TEWL)
Cavallini, Gazzola, and Vaienti (2012)	Does not address adhesive remover
Cooke et al. (2018)	Does not address adhesive remover
Cooper (2011)	Evaluates a single product, Appeel Sterile Sachet
Cousins (2014)	Narrative review
Cressey et al. (2017)	Survey of patients with peri-stoma dermatitis
Darmstadt and Dinulos (2000)	Narrative review
Denyer (2011)	Narrative review, that promotes a specific product
Hadfield, De Freitas, ra, and Bradbury (2019)	Narrative review, addresses adult skin care
Jacobi, Meykadeh, Sterry, and Lademann (2003)	Does not answer the question, does not address silicone
Johnson (2016)	Consensus statement
Jones et al. (2018)	Case studies
Kiat-amnuay, Gettleman, Khan, and Goldsmith (2000)	Adult maxillofacial prostheses
Kiechl-Kohlendorfer, Berger, and Inzinger (2008)	Does not answer the question. Compared water in oil emollient vs. olive oil cream vs. control
Lund (2014)	Narrative review
McNichol, Lund, Rosen, and Gray (2013)	WOC nurses' consensus statement based on AWHONN (2nd edition) AWHONN is now in the 4th edition)
Mustoe and Gurjala (2011)	Does not answer the question, addresses anti scar therapies
Myers AND Ballantyna (1982)	LD 50 in rabbits and rats
O'Neil and Schumacher (2014)	Case presentation, pectin barrier
Pailler-Mattei, Guerret-Piecourt, Zahouani, and Nicoli (2011)	Does not answer the question. Assesses the electric and intrinsic shear strength
Parks (2009)	Letter to the editor
Rudoni (2008)	Adult ostomy care
Sanders, Young, McAndrew, and Kenny (2007)	Does not assess silicone
Shannon and Chakravarthy (2009)	Adult
Sibbald, Campbell, Coutts, and Queen (2003)	Narrative review
Voegeli (2008)	Narrative review
White (2014)	Case study

Methods Used for Appraisal and Synthesis

[a]Rayyan is a web-based software used for the initial screening of titles and / or abstracts for this analysis (Ouzzani, Hammady, Fedorowicz & Elmagarmid, 2017).

[b]The Appraisal of Guidelines Research and Evaluation II (AGREE II) is an international instrument used to assess the quality and reporting of clinical practice guidelines for this analysis (Brouwers et al. 2010).

[c]The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram depicts the process in which literature is searched, screened, and eligibility criteria is applied (Moher, Liberati, Tetzlaff, & Altman, 2009).

[a]Ouzzani, M., Hammady, H., Fedorowicz, Z., & Elmagarmid, A. (2016). Rayyan-a web and mobile app for systematic reviews. *Systematic Reviews, 5*(1), 210. doi:10.1186/s13643-016-0384-4

[b]Brouwers, M.C. et al. for the AGREE Next Steps Consortium. (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Canadian Medical Association Journal, 182*, E839-842. Retrieved from https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf

[c]Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 **For more information, visit www.prisma-statement.org.**

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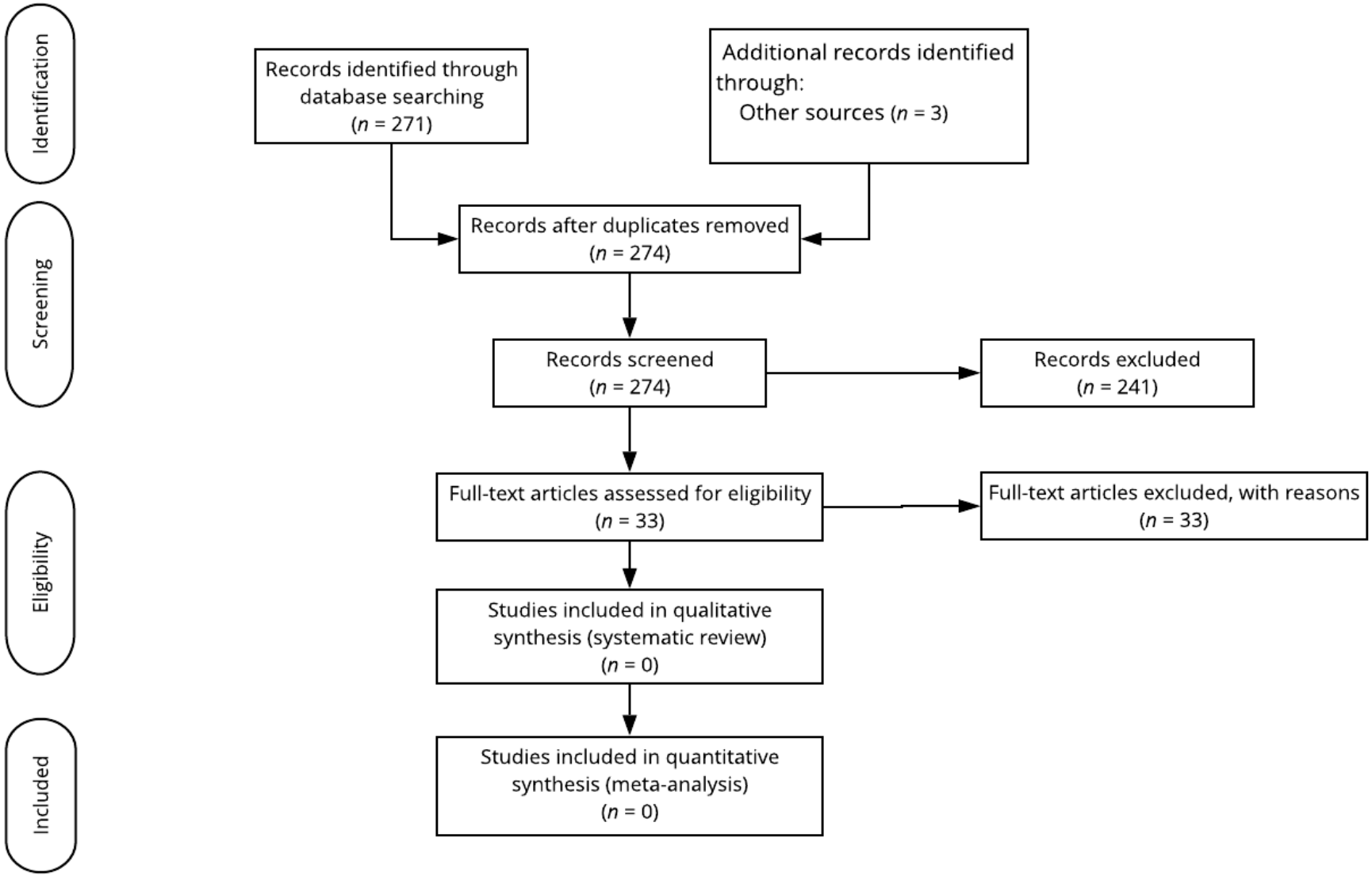

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA)[c]

Table 1
Toxicology Results for Hexamethyldisiloxane

Route	Species	Number in population (gender)	Lethal dose 50 (LD50) or median lethal dose. It is the amount, usually is ml/kg to kill 50% of the test population.
Oral	Sprague Dawley rats	10 (5 male)	> 8 ml/kg
Percutaneous	New Zealand White rabbits	8 (4 male)	8-16 ml/kg under occlusive dressings for 24 hours > 16 ml/kg
Inhalation	Sprague Dawley rats	10 (5 male)	Short exposure with vapor near saturation in a sealed chamber. Lethal Time 50 (LT50)- 15-20 minutes
Skin irritation	New Zealand White rabbits	6 (gender not specified)	0.5 ml dose under occlusive dressings for a 4- hour period No irritation was observed
Eye irritation	New Zealand White rabbits	6 (gender not specified)	0.1 ml dose placed into lower conjunctival sac of one eye minor conjunctivitis

Note: Adapted from Myers and Ballantyna (1982)

Table 2.
Product Components by Weight

	Hexamethyldisiloxane	Other Components
Adapt No Sting Universal Remover Wipe	100% by weight	
Cavilon™ No Sting Barrier Film	41-59% by weight	Foam applicator - 30-40% by weight Isooctate - 4-17% by weight Acrylate Terpolymer 1-8% by weight Polyphenylmethylsiloxane Copolymer - 0.1-4% by weight

Note: Adapted from 3M (2012), Hollister (2018).

Table 3.
Comparison of Selected Information from Safety Data Sheets

	Medi-Sol Adhesive Remover	Cavilon™ No Sting Barrier Film	ADAPT Adhesive Remover
Ingredients	• Proprietary information	• Hexamethyldisiloxane • Foam applicator • Isooctane • Acrylate Terpolymer • Polyphenylmethylsiloxane	• Hexamethyldisiloxane
First Aid Measures:			
• After inhalation	• Move to fresh air	• Move to fresh air	• Move to fresh air
• After skin contact	• Remove affected clothing, wash skin with soap and water	• No need for first aid expected	• No effects expected
• After eye contact	• None reported	• Flush eyes with large amounts of water	• Flush eye with large amounts of water for 15-20 minutes
Precautions for Safe Handling	• Avoid prolong skin contact. Wash affected skin after using the product	• Extremely flammable liquid and vapor	• Highly Flammable liquid and vapor
Exposure Controls/Personal Protection	• Avoid breathing mist • Gloves recommended • Goggles recommended	• Not reported	• Avoid breathing mist
Physical and Chemical Properties	• Clear orange color fluid • Citrus odor • Fluid	• Clear fluid on applicator or wipe • Odorless • Fluid	• Aerosol • Colorless • “Characteristic” odor
Toxicological Information	• Mild skin irritant • Mild eye irritant • No sensitizing effects known	• No skin effects expected • Mild eye irritation • Respiratory tract irritation	• Not classified • Skin corrosion/irritation • Eye toxicity/irritation • Respiratory or skin sensitization
Target Organ Effects	• Not reported	• Central Nervous System – • Liver effects after prolonged exposure	• Not classified • Target organ effect either single exposure or repeated exposure

Note: Adapted from 3M (2012), Hollister (2018), and Orange-Sol (2015).

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