

# **Isothiazolinone White Paper**

## **Background**

Isothiazolinones are preservatives commonly found in many consumer products in the U.S. and in other countries, including cleaning products, cosmetics, and water-based paint. Isothiazolinones are a group of heterocyclic sulphur-containing compounds (Alexander et al., 2002). There are several members of the isothiazolinone family, including methylisothiazolinone (MI), methylchloroisothiazolinone (MCI), benzisothiazolinone (BIT), and octylisothiazolinone (OIT). Isothiazolinones contain an activated N-S bond that reacts with cellular nucleophiles, which is the mechanism of their biocidal activity. MCI has an additional chlorine, which increases its microbial efficacy (Alexander et al., 2002). These preservatives have a low molecular weight, and can penetrate the skin. Their reactivity with cellular nucleophiles, which provides biocidal activity, also allows them to react with cellular proteins, causing a sensitization reaction (Basketter et al., 1999).

There are many consumer products that contain isothiazolinones, including products that are intended to contact or remain on skin, such as cosmetics, hair care products, soaps/cleansers, sunscreens, and cleaning wipes (Zirwas et al., 2017). Isothiazolinones are commonly used in combination in formulations because they vary in stability and efficacy. For example, MCI/MI has a broad spectrum efficacy against bacteria, algae, and fungi. BIT has a narrower range of targets but is useful for longer term preservation (Williams, 2007). Therefore, many products contain combinations of isothiazolinones, such as MI and BIT, in order to preserve products.

MCI/MI was introduced as a preservative in consumer and industrial products in the 1980s, and reports of allergic contact dermatitis (ACD) followed (de Groot and Herxheimer, 1989; Zirwas et al., 2017). By the mid to late 1980s, sensitization rates in the general population had risen to approximately 5% (Alexander et al., 2002). Studies found that MCI, which is chlorinated, was more potent than the non-chlorinated isothiazolinones. This was demonstrated in animal and human studies that were conducted to determine the potency of the isothiazolinones (Alexander et al., 2002). A Guinea Pig Maximization Test reported that the highest tested non-sensitizing dose for MCI/MI (3:1) was 30 ppm; however, the highest tested non-sensitizing dose of a blend of MI/BIT (1:1) was 245 ppm. Similarly, local lymph node assay studies reported the threshold to produce significant sensitization for MCI was ~0.01%, while the threshold for MI was 0.4% and BIT was 10% (Basketter et al. 1999; Alexander et al., 2002). Human patch testing further confirmed that MCI is more potent than the non-chlorinated isothiazolinones. Thresholds for sensitization for MCI were reported in humans at 10-20 ppm (0.0001-0.002%), while thresholds for non-chlorinated isothiazolinones ranged from 250 ppm to 1000 ppm (0.025-0.1%; Alexander et al., 2002). In 1992, the US reduced allowable concentrations of MCI in cosmetic formulations to 7.5 ppm, in order to prevent cases of sensitization.

In the early 2000s, as use of MCI decreased due to sensitization concerns, use of MI increased. MI had been shown to be a less potent sensitizer, while still able to protect products from microbial contamination. However, as MI use became more prevalent, increasing reports of ACD followed. In 2013, MI was named by the American Contact Dermatitis Society as Contact Allergen of the Year

(Castando-Tardana and Zug, 2013). In 2013-2014, the North American Contact Dermatitis Group conducted patch testing of 4,860 patients with possible ACD for MI or MCI sensitization and reported that 11.9% of tested individuals were allergic to one or both isothiazolinones (Zirwas et al., 2017). However, other studies have reported sensitization rates in the general public to isothiazolinones between 2-4% (Lundov et al., 2013; Lundov et al., 2014). Currently, MI is allowable in leave-on and wash-off cleaners/cosmetics up to 100 ppm in the US. Occupational contact dermatitis to isothiazolinones has also been reported in laboratory workers and painters (Young et al., 2004; Hardcastle and Gawrodger, 2005). Sensitization rates in painters to MCI/MI have been reported at 10% (Mose et al., 2012).

While the majority of publications associated isothiazolinones with dermal reactions following direct dermal exposure, a limited number of cases of sensitization from airborne exposure to water-based paints have also been reported (Lundov et al., 2014). ACD clinically manifests as eczema on areas of exposed skin, such as the face and neck. In cases of airborne ACD, there is no known direct skin contact with the allergen, but eczema/hives/rash develops in areas that are not covered by clothing. Isothiazolinones are somewhat volatile and can emit from a freshly painted surface for several weeks after application. MI emission has been reported to peak within hours of application but to continue to emit for 42 days (Lundov et al., 2014). There have been clinical diagnoses of airborne allergic contact dermatitis in people following inhalation exposure to volatiles in paint (Jensen et al., 2006; Amsler et al., 2017; Santos and Goossens, 2007). It is likely that people reporting airborne contact dermatitis were sensitized to isothiazolinones from a previous direct contact to any number of isothiazolinone-containing products, and then subsequently experienced an elicitation reaction from airborne isothiazolinones emitted from paint.

A limited number of reports of respiratory symptoms, such as difficulty breathing or rhinoconjunctivitis, have also been reported in the literature. In a recent publication, 20% of people with known MCI and/or MI sensitization (dermal symptoms) also reported respiratory symptoms, such as dyspnea, cough, asthma, sinusitis/rhinitis. This study included 44 total participants, of which 10 people reported respiratory symptoms (~20%) (Amsler et al., 2017). There are also a number of case reports in the literature of respiratory symptoms, such as dyspnea, related to exposure to isothiazolinones (Alwan, et al. 2014; Bourke et al., 1997; Herry et al., 2016).

## **Environmental Benefit of Isothiazolinones**

Isothiazolinones are used to prevent mildew growth in water based coatings; thereby increasing the shelf life of the product (Schwensen et al., 2014). Isothiazolinones were introduced as a preservative to replace formaldehyde emitting preservatives. There are currently no known technical replacements for isothiazolinones.

## **Allegations of sensitization**

[ ] has reported 9 allegations of possible allergic reactions regarding architectural coatings under TSCA section 8(e) (EPA case number 8EHQ-14-19743). A summary of reported allegations can be found in Table 1. These allegations occurred from 2011-2018. While there are some differences in the symptoms reported, they all are consistent with sensitization/allergic reaction. In most cases, skin reactions, such as red, itchy skin, rash and/or hives were reported, which are symptoms commonly associated with ACD. There were also 2 cases of possible respiratory reactions alleged to be associated with these coatings. The products involved in these cases all contain very low levels of isothiazolinones. The coatings in these cases were not proven to be the cause of the reported reactions. Further, the reactions may not, in all cases, meet the criteria to be considered a significant adverse reaction for purposes of TSCA section 8(c). However, out of an abundance of caution, [ ] decided to report these cases under TSCA 8(e) and disclose the levels of isothiazolinones present in the coatings. The SDS for the products in the first 8 allegations did not include a warning for sensitization at the time the allegation occurred, because the levels of isothiazolinones are well-below the Hazard Communication thresholds. There is a warning for isothiazolinone sensitization on the SDS of the most recent allegation. Voluntary warnings are being added to [ ] SDS for isothiazolinones at low levels as a matter of good product stewardship (see Recommendations section below).

**Table 1. Allegations of sensitization reported to US EPA under TSCA 8(e)**

<b>Date</b>	<b>Product Name</b>	<b>Allegation</b>	<b>Isothiazolinones Content</b>
8/10/2011	[ ]	Respiratory irritation, difficulty breathing. Treated at Emergency Room with prednisone/albuterol	1,2-benzothiazolone (BIT) 0.025%; MCI/MI (3:1)0.00015%
6/13/2014	[ ]	Hives, wheezing. Treated at hospital with prednisone, EpiPen®.	1,2-benzothiazolone (BIT) at 0.0069%; MCI/MI (3:1)0.00019%
11/26/2014	[ ]	Itchy rash. Treated with EpiPen® and Benadryl® at Emergency Room.	1,2-benzothiazolone (BIT) at 0.0088%
3/17/2017	[ ]	Shortness of breath. Treated at hospital with inhaler and steroids.	1,2-benzothiazolone (BIT) at 0.0054%; 2-methyl-4-isothiazolin-3-one (MI) at 0.0134%; CMIT/MIT (3:1)0.00025%
6/15/2017	[ ]	Red, itchy skin 3 days after paint application.	1,2-benzothiazolone (BIT) at 0.00765%; 2-octyl-2-H-isothiazol-3-one (OIT) at 0.00896%; 2-methyl-4-isothiazolin-3-one at 0.00827%; MCI/MI (3:1)I at 0.000142%
10/30/2017	[ ]	Hives on stomach, legs and 1 hand after applying coating to deck.	1,2-benzothiazolone at 0.00919%; 2-methyl-4-isothiazolin-3-one at 0.00865%
12/29/2017	[ ]	Swelling on left side of face after getting coating on hand.	5-chloro-2-methyl-4-isothiazolin-3-one (MCI) at 0.00115%, 2-methyl-4-isothiazolin-3-one (MI) at 0.0066%, and 1,2-benzisothiazolone (BIT) at 0.00625%.
1/19/2018	[ ]	Red, itchy skin on arms and chest.	1,2-benzothiazolone (BIT) at 0.00675%; 2-methyl-4-isothiazolin-3-one (MI) at 0.00675%; MCI/MI (3:1) at 0.000001%
5/15/2018	[ ]	Rash on face and neck	1,2-benzothiazolone at 0.00765%; %; 2-methyl-4-isothiazolin-3-one at 0.00827%; 2-octyl-2-H-isothiazol-3-one at 0.00896%; Isothiazolinone solution at 0.000142%

## **Recommendations**

In the absence of a suitable technical replacement for isothiazolinones, [ ] has decided to add a warning to the SDS for all products containing isothiazolinones at these low levels. The warnings are being added to SDS for all products containing the following isothiazolinones in the following ranges:

<b>Substance Name</b>	<b>CAS Number</b>	<b>GHS SDS/Labels</b>
Methylchloroisothiazolinone/Methylisothiazolinone (3:1) or MCI/MI (3:1)	55965-84-9	0.00015-0.1%
Dichlorooctylisothiazolinone (DCOIT)	64359-81-5	0.0025 – 0.1%
Benzisothiazolinone(BIT)	2634-33-5	0.005 – 0.1%
Octylisothiazolinone (OIT)	26530-20-1	0.005 – 0.1%
Methylisothiazolinone (MI)	2682-20-4	0.01 - 0.1%

This decision affects the SDS of more than [ ], as these products contain at least 1 isothiazolinone in the ranges listed above. These products will have a warning for isothiazolinones in the SDS in Section 2, Supplemental Label Elements, which will state “Contains isothiazolinones. May cause allergic reaction”. If a product contains isothiazolinones in the listed range, then the supplemental warning will appear in Section 2. If the range listed above is exceeded, the mixture will be classified as a skin sensitizer. The thresholds were set based on the known differences in sensitizing potency between the different isothiazolinones. While this warning is not required, [ ] is adding this warning as a matter of good product stewardship. All the products for which allegations were previously submitted will now have warnings for isothiazolinones, as they all contain isothiazolinones in the applicable range.

In light of the number of publications in the scientific literature regarding sensitization and isothiazolinones, the allegations already reported to US EPA under TSCA section 8(e), and the addition of a sensitization warning for isothiazolinones to [ ] SDS, [ ] believes the Administrator has been adequately informed of this potential adverse effect. [ ] wishes to discharge the obligation to report future allegations of sensitization under TSCA 8(e), for allegations that are similar both in symptoms and isothiazolinone content, to those already submitted. [ ] will, however, continue to retain otherwise recordable allegations under TSCA section 8(c), in order to continue to monitor any potential trends in these allegations.

## **Summary**

Sensitization reactions to isothiazolinones have been reported in the scientific literature since the 1980s. These reactions are known to occur at very low levels of exposure; however, many consumer products contain isothiazolinones. Isothiazolinones are used in water-based paint as a preservative to extend product shelf life and no technical replacements currently exist. [ ] has reported 9 allegations of sensitization associated with architectural coatings under TSCA section 8(e). [ ] is adding a warning to all SDS containing isothiazolinones at levels below the Hazard Communication threshold, as a matter of good product stewardship. [ ] believes the Administrator has been adequately informed of the

potential health risk associated with isothiazolinones and that no further reporting of these allegations under TSCA 8(e) is necessary.

## References

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<b>IDENTIFIER</b>	<b>8EHQ-14-19743 Supplement 6</b>
<b>CBI Claims</b>	<b>Company Name</b>
	<b>Product Name</b>
	<b>Technical Contact and Authorized Official</b>

- A. Will disclosure of the information likely result in substantial harm to your business competitive position? YES. The identity, job function, position title, telephone number, e-mail address, etc. of every [ ] employee is non-public information, and it is protected from disclosure per company policy. All non-public information is a valuable asset to [ ] and could be of interest to a competitor. For example, a competitor could target the individual to try to elicit proprietary technical or financial information, or to recruit that individual, causing [ ] to lose that person's expertise. Alternatively, the individual could be subject to harassment from the media or a non-governmental organization (NGO) who has an agenda against members of the chemical industry. The reputation of [ ] might be damaged as a result, which could deter customers and harm [ ] businesses.
- B. To the extent you have disclosed information to others (both internally and externally), what precautions has your business taken? Please identify any measures or internal controls your business has taken to protect the information claimed as confidential.
- Non-disclosure agreement required prior to access. YES
  - Access is limited to individuals with a need-to-know. YES
  - Information is physically secured (e.g. locked in a room or cabinet) or electronically secured (encrypted, password protected, etc.). YES
  - Other internal control measure(s). If so, please explain. YES: Special precautions taken to protect the confidentiality of all non-public information include; the contracting of all employees to maintain confidentiality of all phases of their activities; the maintaining of restricted entry to facilities; the escort of non-company personnel within the facilities; the maintaining of specific security policies for e-mail, travel, visitors, foreign nationals, social media, laptops and electronic devices, trade show attendance, etc.; having resources available (website, helpdesk, training, etc.) to assist employees with adherence to CBI policy.
- C. Does the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? NO: The identity of the Technical Contact for CDR submission is not available to the public.
- D. Does the information claimed to be CBI contain (a) trade secret(s)? NO
- E. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(b)), then please indicate the number of years (between 1-10 years) or specific date of which the claim is withdrawn. NOT APPLICABLE
- F. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? NO





United States Environmental Protection Agency  
Washington, DC 20460

Section 8(e) Notice

This is an original submission:

This is an amendment:

**CERTIFICATION**

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Signature:

XXX

Official Title:

XXX

Contact Person:

XXX

Email Address:

XXX

Date Signed:

XXX

**PART 1**

**Contact Information**

**Submission Information**

Case Number:

Submission Alias:

8EHQ-14-19743 Supplement 6

Date Submitted:

06/22/2018

**Submitter Information**

CBI:

Yes:  No:

Company Name:

XXX

Address:

XXX

	Contact Person: XXX	
	Phone Number: XXX	Email Address: XXX
<b>Technical Contact</b>	CBI: Yes: <input checked="" type="checkbox"/> No: <input type="checkbox"/>	
	Company Name: XXX	Address: XXX
	Contact Person: XXX	
	Phone Number: XXX	Email Address: XXX
<b>PART 2</b>	<b>Chemical Reports</b>	
<b>Chemical Identification</b>	Chemical Report Folder Alias: Isothiazolinone White Paper	
	Mixture Name: Isothiazolinone(s)	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Chemical Identifying #: CASRN: 2634-33-5	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Chemical Name: 1,2-Benzisothiazol-3(2H)-one	
	Percentage (%): 0.1	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Synonym: BIT	
	Chemical Identifying #: CASRN: 2682-20-4	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Chemical Name: 3(2H)-Isothiazolone, 2-methyl-	
	Percentage (%): 0.1	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Synonym: MI	
Chemical Identifying #: CASRN: 26530-20-1	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>	

	Chemical Name: 3(2H)-Isothiazolone, 2-octyl-		
	Percentage (%): 0.1		CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Synonym: OIT		
	Chemical Identifying #: CASRN: 26172-55-4		CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Chemical Name: 3(2H)-Isothiazolone, 5-chloro-2-methyl-		
	Percentage (%): 0.1		CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Synonym: MCI		
<b>Attached Document(s)</b>	Report Study Title: XXX		
	Original Document: XXX	Submission Type: XXX	Sanitized Document: XXX
	Effects: XXX	Endpoints: XXX	
<b>Substantiation</b>	Is the subject chemical (or, in the case of a mixture, the mixture components) on the TSCA Inventory or otherwise available in commerce in the United States? XXX		CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Is the subject chemical or mixture expected to be subject to TSCA and/or is it expected to be used for a non-TSCA purpose? XXX		CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately. XXX		CBI: Yes: <input checked="" type="checkbox"/> No: <input type="checkbox"/>
	For what period do you assert your claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period.  Claim of Confidentiality Event: XXX		CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
<b>Substantiation</b>	Do you assert that disclosure of this information you are claiming CBI would reveal any of the following:		

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<b>(continued)</b>	Confidential processes used in manufacturing the substance? XXX	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	If a mixture, the actual portions of the substance in the mixture? XXX	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Information unrelated to the effects of the substance on human health or the environment? XXX	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	<b>Does the information claimed as confidential appear or is it referred to in any of the following:</b>	
	Advertising or promotional material for the chemical substance or the resulting end product? XXX	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
	Non-confidential material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale)? XXX	
	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>	Professional or trade publications? XXX
	Any other media or publications available to the public or to your competitors? XXX	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>
CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>	Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? XXX	
CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>	If you answered 'Yes' to any of the questions 6A-6D, indicate in the text box below. Indicate below where the information appears and explain why it should nevertheless be treated as confidential: XXX	

### **Paperwork Reduction Act**

The information collection requirements contained in the information collection request (ICR) have been submitted for OMB approval under 15 U.S.C. 2607(e). The ICR prepared by EPA, identified under EPA ICR No. 0794.13 and OMB control number 2070-0046, is available in the docket for the ICR. ICR No. 0794.13 addresses the incremental changes to the currently approved ICR documents that cover the existing reporting and record keeping programs that are approved under OMB control number 2070-0046. An agency may not conduct or sponsor, and a person is not required to, respond to a collection of information unless it displays a currently valid OMB control number.

### **Authority**

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr/>.