



**SAFETY EVALUATION of ingredient for products to apply on skin**

**ISSUED TO:**

Name	Zechstein Minerals B.V.	Zechstein Inside ZI®
Logo		
Address		Transportweg 15 9645 KZ Veendam The Netherlands
Telephone		+31 598 630098
Email		info@Zechsteininside.com
Website		http://www.zechsteininside.com

**Investigation to the safety of the following ingredient:**

Safety statement number:	ZMB/MHIST01102016
Product Name:	ZI® Brine
Chem/IUPAC Name /: Chemical symbol:	Magnesium chloride / MgCl <sub>2</sub>
CAS Number:	7786-30-3
EINECS/ELINCS No:	232-094-6
Restrictions:	Last update 2008 Mar 01 - no restrictions
Product form:	Liquid
Composition:	31%-32% Magnesium chloride dissolved in water
Colour:	Colourless to light yellow solution
Odour:	Characteristic
pH:	4-6
Relative density:	1290 – 1330 g/l
Stability:	Stable under normal conditions
Microbiological quality:	No growth of microorganism due to hyper salinity
Impurities/ Trace elements:	Negligible
Undesirable effects:	No undesirable effects known in case of normally usage of product.
Product use:	Applied on skin: daily, 5 – 10 sprays; 1 – 2 grams per event
Exposure:	MoS >> 100 Safe for use as ingredient in finished products
Shelf life of ingredient:	More than 2 years
Ingredient on market:	Since 2006
Units sold:	> 4.000.000 kg
Safety related claims registered since:	-

**Conclusion:**

We conclude that Zechstein Minerals Brine (ZI Brine®), produced in accordance to the certified Zechstein Inside® batch protocol (ZI®), is safe to be marketed.

This assessment has been conducted according to the guidelines laid down in Regulation (EC) No 1223/2009 of the European parliament and of the council, of 30 November 2009 on cosmetic products. From 11 July 2013, this Regulation replaces the "Cosmetics Directive". The provisions of the Regulation aim at ensuring that consumers' health is protected and that they are well informed by monitoring the composition and labelling of products. The Regulation also provides for the assessment of product safety and the prohibition of animal testing.

The production of the Zechstein Minerals Brine (ZI Brine®) by Nedmag Industries Mining & Manufacturing B.V. (P.O. Box 241 (Billitonweg 1) 9640 AE Veendam, the Netherlands) is in accordance to the certified Zechstein Inside® batch protocol. The Zechstein Inside® batch protocol guarantees the highest natural quality of magnesium chloride from the Zechstein Magnesium chloride source and ensures that the raw ingredients meet the safety requirements for topical applications as defined in Regulation (EC) No 1223/2009 of the European parliament and of the council of 30 November 2009 on cosmetic products.

It is considered in the present state of knowledge, assuming production according current GMP [Regulation (EC) No 1223/2009], ZI Brine® should not cause damage to human health when stored and used under normal and reasonable foreseeable conditions of use.

This evaluation is based on the starting points and specific expertise of the assessor and the consideration of the general toxicological profile of the single ingredients used, their chemical structure and their level of exposure. If during marketing, an abnormal high number of serious cases of undesirable effects for human health are induced by this product, the undersigned assessor should then be informed of these effects and may consider a new evaluation of the safety of the product.

Further supporting information is available to regulatory authorities upon request from the issued company.

Safety assessor:



R. M. Danel, MD

Date: 1 November 2018

## Starting Points for this Safety Evaluation (SCCS/1564/11 9<sup>th</sup> revision Notes of Guidance)

1. Safety data supplied by the raw material supplier will be used for the safety evaluation of cosmetic products. Additionally, if necessary, safety data available through public accessible databases, will be used.
2. Our potential for judgment, based on our knowledge and experience in the cosmetic industry, will be unconditionally used for the safety evaluation.
3. When raw materials meet the safety requirements based on annexes II/III/IV/V/VI of the Regulation (EC) No 1223/2009 of the European parliament and of the council, of 30 November 2009 on cosmetic products, they are considered to be safe for use in cosmetic products and they will not be subjected during our evaluations to a profound investigation.
4. The evaluation of standard ingredients of cosmetic products supplied by the established suppliers, will be kept to a minimum.
5. The actuality of upcoming safety issues will be based on publications of the SCCS and Colipa.
6. We consider the information that can be derived from safety records dating from 01-01-2000 to present, to be valid for safety evaluations, provided that a significant number of units have been sold to consumers.
7. Safety evaluations will only be carried out on products that at least have passed a thirteen-week stability test at 45°C or a comparable test with acceptable and/or explainable pH changes.
8. (Re)active ingredients will only be qualified safe when a NOAEL is available.
9. Impurities of cosmetic raw materials will be evaluated as being regular ingredients.

## Declaration of Competence Safety Evaluations

Name:	Richard Maurice Danel, MD	1986	Medicine, Medical Degree, Rijksuniversiteit Groningen
Date of Birth:	Sliedrecht, 16 juli 1955		
Nationality:	Dutch		
		BIG Registration:	3112197 / arts / 19020564001 / bul / 27031986
		Relevant Expertise:	
<u>The Netherlands</u>		2009 –	Chair of Magnesium Health Institute (MHI) <i>Stichting Zechstein Zout Expertise Centrum</i>
Adres:	Woldweg 74		
Postcode:	9734 AE		
Plaats:	Groningen, The Netherlands		
<u>Canada</u>			
Address:	1548 West Hastings Street		
Postal code:	V6G 3J4		
Residence:	Vancouver, BC, Canada		
Phone:	+31 6 112 33 071		
E-mail:	MHI@soundhealth.onmicrosoft.com		
			<ul style="list-style-type: none"> <li>- Responsible for research, registration and patenting of Magnesium products for healthcare applications.</li> <li>- Development of topical applications</li> <li>- Development of clinical / therapeutic applications, e.g. for Psoriasis patients</li> <li>- Lecturing for healthcare providers about and involvement with issues worldwide related to Mg research, therapy, applications and industry</li> </ul>