

## PRODUCT REGULATORY SUMMARY

# Crodamide ER-BE-(HU)

DATE: 04/08/2021

### COMPOSITION

Erucamide (CAS No. 112-84-5)

\*concentrations are proprietary

### ALLERGENS

Crodamide ER-BE-(HU) is not produced using nor expected to contain any of the 26 fragrance allergens listed in Annex III of Regulation (EC) No 1223/2009.

Additionally, Crodamide ER-BE-(HU) is not produced using nor expected to contain any of the common allergens listed below in accordance with Regulation (EU) No. 1169/2011 and the FDA Food Allergens Guidance.

- Cereals containing gluten and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof
- Tree nuts (walnuts, pecans, etc.) and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulfur dioxide and sulfites
- Lupin and products thereof
- Mollusks and products thereof

### ANIMAL CONTENT

Crodamide ER-BE-(HU) is manufactured completely from synthetic or plant materials and does not contain any raw materials that are produced from, or substances derived from animal origin.

While Crodamide ER-BE-(HU) is not certified to be Kosher, we believe it to be compliant with Kosher regulations. The origin and source of the raw materials used for production of these products are chemical and mineral. No animal source raw materials are used.

Moreover, Crodamide ER-BE-(HU) is not derived from specific-risk materials as defined in European Commission Decision 97/534/EC. The manufacturing process does not use any ingredient of animal origin nor does this product come in contact with animal-derived products during storage and transportation.

Therefore, Crodamide ER-BE-(HU) is expected to be free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

## **CALIFORNIA PROPOSITION 65**

Crodamide ER-BE-(HU) is not expected to contain any substances known to the State of California to cause cancer, birth defects, or other reproductive harm, at levels which would require a warning under California Proposition 65, Safe Drinking Water and Toxic Enforcement Act of 1986 as of March 19, 2021.

## **CALIFORNIA TRANSPARENCY IN SUPPLY CHAINS ACT**

Barentz North America, LLC fully supports California's efforts to protect human rights and enforce ethical labor practices under the California Transparency in Supply Chains Act of 2010 (SB 657).

Barentz is proud of our reputation and record for integrity and respect in dealing with our own employees and expects nothing less of our suppliers in their dealings with their workforce. We work closely with our suppliers to ensure that they do not engage in or support forced labor or unlawful child labor.

We are committed to ensuring that working conditions in our supply chain are safe, that workers are treated with respect and dignity, and that manufacturing processes are environmentally and socially responsible. Additionally, we expect our suppliers to adopt and maintain terms of employment for their employees that comply with local law and the requirements of our Supplier Code.

## **CARCINOGENS, MUTAGENS, TOXIC FOR REPRODUCTION (CMR)**

Crodamide ER-BE-(HU) is not expected to contain any carcinogens, mutagens, or toxic for reproduction (CMR) substances outlined within Annex II of Council Directive 76/769/EEC.

## **CERTIFICATE OF ORIGIN**

Crodamide ER-BE-(HU) is produced in the United Kingdom. Therefore, this product does not qualify for the United-States-Mexico-Canada Agreement (USMCA).

## **CONEG (DIRECTIVE 94/62/EC)**

None of the toxic elements—Cadmium, Hexavalent Chromium, Lead, or Mercury—are used as raw materials nor deliberately added during the manufacturing process of Crodamide ER-BE-(HU).

With this in mind, Crodamide ER-BE-(HU) is expected to be free from the above-mentioned toxic elements. Any incidental amount would be expected to be less than 100 parts per million (ppm).

## **CONFLICT MINERALS**

Barentz North America LLC is committed to being a responsible corporate citizen and is opposed to human rights abuses. As part of that commitment, Barentz North America LLC seeks to source products, components, and materials from companies that share our values around human rights, ethics, and environmental responsibility.

In August 2012, the U.S. Securities and Exchange Commission ("SEC") adopted final rules implementing Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Conflict Minerals Rule"). Under these rules, publicly traded companies must annually report to the SEC whether the products they manufacture or contract to manufacture contain "conflict minerals" originating from the Democratic Republic of the Congo (the "DRC") or adjoining countries. Revenue from the mining and transport of these conflict minerals is believed to be financing or benefiting groups that are responsible for human rights violations. "Conflict minerals" refers to columbite-tantalite (coltan), cassiterite, gold, wolframite and the derivatives tantalum, tin, and tungsten, without regard to the location or origin of the minerals or derivative metals.

Barentz North America LLC supports industry-wide efforts to identify, reduce, and hopefully eliminate the use of conflict minerals originating from the DRC and adjoining countries to the extent believed to be financing or benefiting groups committing human rights violations. Barentz North America LLC is committed to complying with any applicable requirements under the Conflict Minerals Rule.

Suppliers to Barentz North America LLC are expected to establish their own conflict minerals policies, due diligence frameworks, and management systems that are designed to prevent conflict minerals originating from the DRC or an adjoining country, to the extent that they benefit groups committing human rights violations, from being included in the products sold to Barentz North America LLC. In the event Barentz determines that a supplier has failed to develop and implement reasonable steps to comply with this Policy, Barentz North America LLC reserves the right to take appropriate actions, which may include discontinuing the business relationship with the supplier.

## **EU FOOD CONTACT (EUROPE)**

Crodamide ER-BE-(HU) complies with the compositional requirements set forth in Commission Regulation (EU) 10/2011, as amended. No specific migration limit is listed for the use of this product. For substances which no specific migration limit is provided, a generic specific migration limit of 60 mg/kg applies.

Crodamide ER-BE-(HU) meets the quality and general principles outlined in Regulation (EC) 1935/2004 and 2023/2006. These regulations require a quality approach to manufacturing which is illustrated by Barentz North America LLC's ISO 9001 and Responsible distribution certifications.

## **FDA FOOD CONTACT (UNITED STATES)**

Crodamide ER-BE-(HU) complies with the requirements of the Code of Federal Regulation, 21 CFR outlined in the following chapters.

- §175.105
- §175.300 (b)(3)(xxxi)
- §175.320(b)(3)(iii)
- §176.180(b)(2)
- §176.210(d)(2)
- §177.1200(c)
- §177.1210(b)(5)<sup>1</sup>
- §177.1350(iv)
- §177.1390(c)(2)(ii)<sup>2</sup>
- §177.1395
- §177.1400<sup>3</sup>
- §177.2210<sup>4</sup>
- §177.2600(c)(4)(ix)<sup>5</sup>
- §178.3120(d)(3)
- §178.3860
- §179.45(d)(2)(i)<sup>6</sup>

<sup>1</sup>For use only at 5% by weight of closure sealing gasket composition.

<sup>2</sup>Substances complying with §175.105 of this chapter may be used in these constructions provided they are separated from the interior (food contact) layer(s) by a functional barrier as discussed under paragraph (a) of this section.

<sup>3</sup>For use only with Substances identified in and used in compliance with §177.1200(c).

<sup>4</sup>Limitations as prescribed in §177.2600.

<sup>5</sup>Total not to exceed 5% by weight of rubber product.

<sup>6</sup>For use only at levels not to exceed 1% by weight of polymer.

## **GB 9685 FOOD CONTACT (CHINA)**

Crodamide ER-BE-(HU) complies with the compositional requirements set forth in China's GB9685 Hygienic Standard, as amended<sup>1</sup>. No specific migration limit or maximum residual limit is given.

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<sup>1</sup>For use in PE, PP, PVDC, and PLA. Dosage as necessary.

## GLOBAL INVENTORY STATUS

To the best of our knowledge, Crodamide ER-BE-(HU) is either exempt from or can be found as a positive listing on the chemical inventories listed below

- Australia— Australian Inventory of Chemical Substances (AICS)
- Canada — Domestic Substances List (DSL)
- China — Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)
- Europe — European Inventory of Existing Chemical Substances (EINECS)
- New Zealand— New Zealand Inventory (NZIoC)
- The Philippines— Philippine Inventory of Chemicals and Chemical Substances (PICCS)
- United States— Toxic Substances Control Act Inventory (TSCA)

## GLUTEN

Crodamide ER-BE-(HU) does not contain nor is it expected to come into contact with gluten or products containing gluten.

## IMPURITIES & ADDITIVES

Crodamide ER-BE-(HU) is not manufactured using nor expected to contain any of the substances listed below in detectable amounts.

- Alkyl Phenol Ethoxylates – Octyl and Nonyl
- Asbestos
- Bisphenol compounds
- CMR Compounds
- Formaldehyde
- GMOs
- Nanomaterials (300 nm or less)
- Natural Rubber
- Nonylphenols
- Octylphenols
- Organotin compounds
- PCBs
- Perfluoroalkylated Substances
- Phthalates
- Substances in Commission Regulation (EC) No 1895/2005 – BADGE/BFDGE/NOGE

## REACH

Crodamide ER-BE-(HU) has been registered in accordance with REACH regulation (EC) No 1907/2006 by the manufacturer of this product.

Please contact your Barentz North America LLC account manager to discuss any need for REACH Only Representative coverage.

## RoHS

The below substances listed in EU Directive 2015/863, also known as Restriction of Hazardous Substances (RoHS) 3, have not been intentionally added nor are they expected to be present in concentrations greater than the specified prohibited amounts in Crodamide ER-BE-(HU).

- Cadmium (<100 ppm, 0.01%)
- Lead (<1000 ppm, 0.1%)
- Mercury (<1000 ppm, 0.1%)
- Hexavalent chromium (<1000 ppm, 0.1%)
- Polybrominated biphenyls (PBB) (<1000 ppm, 0.1%)
- Polybrominated diphenyl ethers (PBDE) (<1000 ppm, 0.1%)
- Bis(2-ethylhexyl) phthalate (DEHP) (<1000 ppm, 0.1%)
- Butyl benzyl phthalate (BBP) (<1000 ppm, 0.1%)
- Dibutyl phthalate (DBP) (<1000 ppm, 0.1%)
- Diisobutyl phthalate (DIBP) (<1000 ppm, 0.1%)

## SUBSTANCES OF VERY HIGH CONCERN (SVHC)

None of the substances contained in the Candidate List of Substances of Very High Concern (SVHC) as of January 19, 2021, are intentionally used nor added in the manufacture of Crodamide ER-BE-(HU).

Because the presence of the substances in the Candidate List are not expected under normal conditions, the absence has not been checked by tests.

## DISCLAIMER

The information contained in this document is based upon data obtained from the manufacturer. This information is offered only as a guide to the handling of this specific material and conditions. The use and handling of this material may require alternate and additional considerations. No representation or warranty of any kind whatsoever is given or implied by Barentz North America LLC with respect to any information contained herein. In no event or circumstance shall Barentz North America LLC be liable for any damages, losses, liabilities or injuries of any kind whatsoever arising from any information contained herein including, without limitation, all indirect, special or consequential damages or losses which may result from the information contained herein.