Document Ref: POL.QUAL.004 Issue Date: 07/10/2021 Issue Number: 007 Title: TNS Regulatory Statement



Page 1 of 5

Regulatory Information

Totally Natural Solutions Ltd provide a range of natural hop products prepared from hop cones and hop pellets using only physical techniques.

Totally Natural Solutions can work with you to provide tailored technical information regarding the regulatory status and labelling of your products containing their ingredients.

The following tables detail the product ranges which divide the classification of the products into two distinct categories which aim to identify the primary and secondary use of the products. The primary use of the product is intended for use within the brewing industry and secondary use is aimed towards flavouring for the food and drink industry. Secondary designation should be fully determined by the end user, dependent upon product use within the final application.

For the core range the following regulatory/labelling information may apply.

Document Ref: POL.QUAL.004 Issue Date: 07/10/2021 Issue Number: 007 Title: TNS Regulatory Statement



Page **2** of **5**

TNS hop oil-based products:

Product	Description	Regulation	Primary Classification	Secondary Classification
HopBurst®	Dry hop character provided by whole hop oil in mono propylene glycol carrier	EC – 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Flavouring preparation
HopShot [®]	Fractionated Hop Oil Extract in mono propylene glycol carrier			
HopSensation®	Late hop character provided by hop oil extract in mono propylene glycol carrier	US – 21CFR 182.20	Natural Extractive and recognised as GRAS by the FDA	Natural Extractive and recognised as GRAS by the FDA
Hop Oil	Whole Oil extracted from hops	EC – 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Flavouring Preparation
		US – 21CFR 182.20	FEMA 2580	FEMA 2580
HopPlus®	Hop Oil extract blended with natural flavours (fruits, herbs etc)	EC – 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Natural Flavouring substance
		US – 21CFR 182.20	Natural Extractive WONF (with other natural flavours) and recognised as GRAS by the FDA	Natural Extractive WONF (with other natural flavours) and recognised as GRAS by the FDA
HopZero®	Hop oil extract for low alcohol beverages	EC-1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Flavouring preparation

Document Ref: POL.QUAL.004 Issue Date: 07/10/2021 Issue Number: 007 Title: TNS Regulatory Statement



Page **3** of **5**

TNS Hop products made from CO₂ extract of hop pellets for bittering use:

Product	Description	Regulation	Primary Classification	Secondary Classification
HopAlpha® NISO 25%	A 25% aqueous solution of natural iso alpha acids, prepared without inorganic catalysts	EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Flavouring substance
HopAlpha [®] ISO 20%	A 20% standardised aqueous solution of iso alpha acids	EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Other Flavouring
HopAlpha® ISO 30%	Alpha acids have been isomerized to iso-alpha acids and standardized to 30% conc.	EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Other Flavouring
HopAlpha [®] Rho 30%	A 30% standardised solution of reduced iso alpha acids.	EC - 1334/2008 EU – 852/2004 (HACCP)		
	A 9% standardised solution of hydrogenated iso alpha acids.		Modified Hop Extract	Modified Hop Extract
Hon∆lnha® Tetra 9%		US – 21 CFR 172.560 (1-6).		
HopAlpha [®] IKE	Isomerised hop extract, including iso alpha acids, beta acids and oils	EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Other Flavouring
HopAlpha [®] Extract	Hop extract containing alpha acids, beta acids and oils obtained by supercritical /liquid CO ₂ extraction.	EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract	Flavouring preparation

Document Ref: POL.QUAL.004 Issue Date: 07/10/2021 Issue Number: 007 Title: TNS Regulatory Statement



Product	Description	Regulation	Primary Classification
HopBeta [®] BAO	Hop Extract, high in Beta acids and Hop Oil but with very low alpha content	EC - 1334/2008 EU – 852/2004 (HACCP) EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract
HopBeta [®] AOE	Hop Extract containing Hop Oils with low levels of alpha and beta acids]
Lion Data [®] 10	A standardized aqueous solution		Hop Extract
HopBeta [®] 10	of beta acids.		
HopBeta [®] DeOiled	Hop Extract high in beta acids but low in alpha and oil content	EC - 1334/2008 EU – 852/2004 (HACCP)	Hop Extract

NaturalSensation®

Product	Description	Regulation	Primary Classification
Natural Sensation	Flavouring for beverages	EC1334/2008 EU – 852/2004 (HACCP)	Flavouring Preparation

Document Ref: POL.QUAL.004 Issue Date: 07/10/2021 Issue Number: 007 Title: TNS Regulatory Statement



Page **5** of **5**

TNS Hop products also comply with regulations on packaging suitability and general food law.

Product	Description	Regulation	Classification
ALL	Suitability of Packaging	EC 1935/2004	Traceable packaging and suitable for food use
ALL	General Food Law	EC 178/2002	Traceability and Withdrawal Systems in place
ALL	GMO	EC 1829/2003 EC 1830/2003	No GMOs used in the production of TNS products
ALL	General Food Law	EC 1019/2008	Water used at TNS is tested and deemed suitable for purpose.
ALL	Pesticide Residues	EC 396/2005	Pesticide residue levels are monitored by our suppliers. The method of processing at TNS reduces the risk of pesticide residue contamination further.
ALL	Nutrition Labelling	EU 1169/2011 21CFR101 9(a), j(4) j(9)	TNS does not test for nutritional data. Our products typically do not contribute to the nutritional value when used for flavouring and to enhance product aromas. Our products fall under the exemptions of the stated regulations.
ALL	Allergen Labelling	EU 1169/2011	As all products are prepared and packed in an allergen free environment. As a result we do not list any allergenic ingredients on products labels in accordance with EU 1169/2011
ALL	Training	EC 852/2004	Food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity
HopBurst [®] , HopShot [®] & HopSensation [®]	Approved use of Propylene Glycol (CAS Reg 57-55-6)	EC 1333/2008 EU – 852/2004 (HACCP)	Propylene Glycol is approved as a carrier and GRAS by the FDA. Safe limit set at 5% in alcoholic beverage