

## Outcome of step 2 of the call for scientific and technical data on the permitted food additive glycerol esters of wood rosins (E 445)

The business operator DRT committed to providing the following data:

TECHNICAL DATA	TIMELINE FOR DATA SUBMISSION
Analytical data on current levels of arsenic, lead, mercury, and cadmium in commercial samples of the food additive E 445	Final report : 19 August 2019
Concentrations of specific impurities identified in EU specifications for glycerol (E 422) – acrolein, butanetriols, chlorinated compounds, 3- monochloropropane-1,2-dio	Interim update : 19 August 2019 Final report : 19 September 2019
Concentrations of specific impurities associated with the glycerol manufacturing process – glycidol, dichlorohydrin, epichlorohydrin	Interim update : 19 August 2019 Final report : 19 September 2019
Glycerol monoesters, free resin acids, and neutrals	Interim update : 19 August 2019 Final report : 19 September 2019

TOXICOLOGICAL DATA: results from an OECD 421 (Reproduction/Developmental Toxicity Screening Test)	TIMELINE FOR DATA SUBMISSION
Pre-study chemistry	To start in June and be complete by late July 2019
14-day preliminary report	Non-GLP draft report October 2019
OECD 421	Histopathology report March 2020 Audited draft report April 2020

The business operator T&R Chemicals committed to providing the following data:

TECHNICAL AND TOXICOLOGICAL DATA	TIMELINE FOR DATA SUBMISSION
Analytical data on current levels of arsenic, lead, mercury and cadmium in commercial samples of the food additive	1 June 2020
The lowest technologically achievable level for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications	
Analytical data on current levels in commercial samples of the food additive E445 of impurities of toxicological concern (e.g. butanetriols, acrolein, chlorinated compounds and 3-monochloropropane-1,2-diol), as identified in the EU specifications of the food additive glycerol (E 422) <sup>4</sup> , which	

can be used in the manufacturing process of E445	
The lowest technologically achievable level for impurities of toxicological concern (e.g. butanetriols, acrolein, chlorinated compounds and 3-monochloropropane-1,2-diol) in order to adequately define their maximum limits in the specifications of E 445	
Analytical data on current levels in commercial samples of the food additive E445 of any impurity present in glycerol (as mentioned in the call for data on the food additive glycerol (E422), which can be used in the manufacturing process of E445	
The lowest technologically achievable level for any impurity which could be formed during the manufacturing processes of glycerol and be present in E445, in order to adequately define their maximum limits in the specifications of E 445	
Analytical data on the concentrations of the toxicologically relevant fractions of 'glycerol monoesters', 'free resin acids' and 'neutrals' from a GEWR equivalent to the GEWR which was subject to the toxicological testing	2 <sup>nd</sup> Quarter 2020
Detailed information on the chemical composition of GEWR originating from <i>P. halepensis</i> and <i>P. brutia</i> (and potentially other pine species), in particular on the concentrations of the toxicologically relevant fractions of 'glycerol monoesters', 'free resin acids' and 'neutrals'.	2 <sup>nd</sup> Quarter 2020
Toxicological rationale documents addressing the EC Call for Data Toxicological data request for reproductive and developmental studies	20 May 2019
The updated 2018 86th Session JECFA GEWR specifications	20 May 2019
U.S. and International Environmental "threatened and endangered species" impact of harvesting stumps from " <i>Pinus Palustris</i> " (Longleaf Pine)	20 May 2019

The business operator Megara Resins committed to providing the following data:

TOXICOLOGICAL DATA	Timeline for Data Submission
ECHA Full reproductive/developmental tox studies	15 May 2019