

NICHIRIN CHEMICAL INDUSTRIES LTD.

320,SENZO 4CHOME,ITAMI,HYOGO,JAPAN

TELEPHONE +81-72-781-0771

TELFAX +81-72-781-3596

To whom it may concern

Residual solvent declaration

NICHIRIN CHEMICAL INDUSTRIES who are manufacturing KICCOLATE ND-2HS (Croscarmellose Sodium) proves the following.

Based on knowledge of our manufacturing process and controlled handling and storage of the referenced shipment there is no potential for specific solvents (Class 1, Class 2 and Class 3) referenced in USP<467>. There is no potential for specific solvents referenced in CPMP/ICH/283/95, and other solvents. Furthermore the organic solvent is entirely not used about processes in the same factory.

Sincerely yours,

Nichirin Chemical Industries Ltd.

K Sasaki

Kouji Sasaki

Quality assurance department manager

September 22, 2017