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Vitenskapskomiteen for mattrygghet/
Norwegian Scientific Committee for Food Safety
Postboks 4404 Nydalen
NO - 0403 Oslo
NORWAY

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Mattilsynet

# RISK ASSESSMENT CONCERNING MIGRATION OF NETSA USED IN PRINTING INKS TO FOOD SIMULANT

## Background

The background for this commission is the risk assessment of 9th November 2004, opinion by the Norwegian Scientific Committee for Food Safety (VKM) concerning migration of N-ethyl-toluenesulfonamide (NETSA) CAS-No. 8047-99-2 from cheese film to food simulant. The main conclusion from the risk assessment is that the lack of toxicological data makes it impossible to rule out possible negative health effects. According to VKM more toxicological data is needed to do a complete risk assessment, leading to the establishment of tolerably daily (TDI) or weekly intake (TWI).

NETSA do have several CAS-numbers; 8047-99-2 for mixtures; N-etyl-o-toluensulfonamid CAS-No 1077-56-1 and 80-37-2; N-etyl-p-toluensulfonamid CAS-No 80-39-7 and N-etyl-m-toluensulfonamid CAS-No 66898-18-8

NETSA is the generic name of the product, Ketjenflex 8 is Axcentive commercial name for it and Santicizer 8 is the old commercial name from the company Monsanto (not in use anymore).

## Commission

The producer of NETSA (CAS No. 8047-99-2) Axcentive Sarl has now carried out toxicological testing and will in short time supply VKM with the complete dossiers. Toxicological study on NETSA is recently carried out also in Sweden. The Norwegian Food Safety Authority herewith asks VKM to carry out a risk assessment based on new toxicological tests on NETSA, respectively performed by Axcentive Sarl and Livsmedelsverket. If possible tolerably daily intake should be established.

According to Axcentive Sarl, studies available are:

- Evaluation of the acute oral toxicity of NETSA in the rat.
- Repeated dose 90-day oral toxicity study with NETSA by daily gavage in the rat.
- Micronucleus evaluation bone marrow from repeated dose 90-day oral toxicity study with NETSA by daily gavage in the rat.
- Ames/Salmonella mutagenicity assay of Santicizer 8 plasticizer CAS No. 8047-99-2.

**Mattilsynet**
**Hovedkontor**

Saksbehandler: Per Fjeldal
Tlf: +47 23 21 67 71
Besøksadresse: Ullevålsveien 76
E-post: postmottak@mattilsynet.no
(Husk mottakers navn)

Postadresse: Hovedkontor mattilsynet.no
Felles postmottak, Postboks 383
2381 Brumunddal
Telefaks: 23 21 68 01

- Evaluation of the mutagenic activity of NETSA in an in vitro mammalian cell gene mutation test with L5I78Y mouse lymphoma cells (with independent repeat).
- Evaluation of the ability of NETSA to induce chromosome aberrations in cultured peripheral human lymphocytes (with repeat experiment).
- Micronucleus test in bone marrow cells of the rat with NETSA

In addition to the above studies, Axcentive Sarl informs that they have calculated the octanol/water coefficient partition according to OECD 117, non GLP analysis. The company also informs that test regarding skin and eye irritation, as well as aquatic toxicity and biodegradability tests have been performed for NETSA.

A toxicological study on NETSA is now also carried out in Sweden. Reference to the study is: TUT-05 9/19/06, Toxikologiutbildningen, IMM, KI, Allmäntoxicitetsstudie av N-etyl-o,p-toluen-sulfonamid (NETSA) på råtta vid daglig peroral tillförsel under 28 dagar. This study has been submitted to VKM for evaluation as part of this risk assessment.

It is to be observed that confidentiality is claimed for the studies. The Norwegian Food Safety Authority assumes that VKM sign appropriate confidential agreements with the respective organisations, which ensures both the need for VKM to have transparency in the risk assessment, and the need for protection of specific and sensitive data in the studies.

**Priority**
This commission should be given normal priority. We request that the opinion is finished during the autumn of 2007. We also ask for the risk assessment to be written in English. References to the former risk assessment may be done without translation to English of more than those parts which is quoted.

Yours sincerely

Per Fjeldal
Adviser

**Copy:**
Axcentive Sarl
Att: Dr. Jean de Barbeyrac
Chemin de Champouse- Quartier Violesi
FR -13320 Bouc Bel Air
France

Livsmedelsverket
Att: Dr. Kettil Svensson
Box 622
SE-75126 Uppsala
Sweden