

**Committee for Risk Assessment**  
**RAC**

Annex 3  
**Records**  
of the targeted public consultation on the the hazard class  
STOT RE of

**butanone oxime; ethyl methyl ketoxime;  
ethyl methyl ketone oxime**

**EC Number: 202-496-6**

**CAS Number: 96-29-7**

CLH-O-0000001412-86-227/F

**Adopted**  
**14 September 2018**

**ANNEX 3 – RECORDS OF THE TARGETED PUBLIC CONSULTATION ON THE THE HAZARD CLASS STOT RE OF BUTANONE OXIME; ETHYL METHYL KETOXIME; ETHYL METHYL KETONE OXIME**

**COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION**

The proposal for the harmonised classification and labelling (CLH) of butanone oxime; ethyl methyl ketone; ethyl methyl ketone oxime was submitted by the German Competent Authority and was subject to a public consultation from 19 July until 4 September 2017. The comments received by that date are compiled in Annex 2 to the opinion.

During its June 2018 meeting (RAC-45), the Committee for Risk Assessment (RAC) agreed that the totality of the observed effects (consistency of effects across the studies and dose response) on the haematopoietic system is sufficient to classify the substance in category 2. RAC agreed to classify the substance as STOT RE 2; H373 (blood system). However, since the STOT RE hazard class was not open for commenting during the public consultation, in order to complete the process transparently, ECHA launched a targeted public consultation on this endpoint after the aforementioned plenary meeting (26 June to 10 July 2018). The opinion was tabled for the adoption at RAC-46 in September 2018.

**Substance name: butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime**

**CAS number: 96-29-7**

**EC number: 202-496-6**

**Dossier submitter: Germany**

**GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
10.07.2018	Poland	<confidential>	Company-Downstream user	1
Comment received				
<p>Butanone oxime jest stosowany w rozpuszczalnikowych mieszaninach alkidowych (farby, pasty, lakiery). Od kilkunastu lat stosujemy ten surowiec do produkcji mieszanin rozpuszczalnikowych na bazie żywic alkidowych w ilości poniżej 0,9% i nie zauważyliśmy by właściwe jego stosowanie miało negatywny wpływ na zdrowie człowieka (brak incydentów cancerogennych). Wprowadzenie zaostrożonej klasyfikacji skutkowałoby wycofaniem z rynku tego surowca z rynku farb i lakierów alkidowych. Jest to zarazem surowiec należący do lotnych związków organicznych i po wyschnięciu powłoki nie będzie go w produkcie ale sama zmiana klasyfikacji wyeliminuje go ze stosowania.</p> <p><b><u>Unofficial ECHA translation:</u></b> <i>Butanone oxime is used in alkyd solvent mixtures (paints, coats and lacquers). We have been using this material at below 0.9% dose to produce alkyd based solvent mixtures for many years now and we have not observed any adverse effects to human health (no carcinogenic incidents) when it is properly used. A stricter classification of this material would result in its withdrawal from the alkyd based paint and lacquer market. Meanwhile it is a volatile organic compound, which means it will not stay in the final product after its surface dries, however its stricter classification would eliminate its use.</i></p>				
RAC's response				
<p>Thank you for your comment. However, as classification is hazard-based, RAC will assess all relevant toxicity data (including from laboratory studies) against the relevant criteria to assess this intrinsic toxicity of butanone oxime.</p>				

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**OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure**

Date	Country	Organisation	Type of Organisation	Comment number
10.07.2018	Belgium	Reconcile REACH Consortium	Industry or trade association	2
Comment received				
<p>Members of the Reconcile REACH Consortium are of the opinion that MEKO does not meet the classification criteria for STOT-RE. Please find the detailed argumentation to support this in the attached letter and annex.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment P-I180 Reconcile MEKO CLH 20180710(2).pdf</p>				
RAC's response				
<p>Thank you for your comment. Having considered the weight of evidence, RAC is of the opinion that the consistent effects observed following exposure of butanone oxime to rats and rabbits provides strong evidence of toxicity to the bloody system. The doses at which these effects were observed were low enough for classification with STOT RE 2.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
05.07.2018	Austria		MemberState	3
Comment received				
<p>The available repeated dose studies indicate that butanone oxime adversely affects the blood system. Effects on the blood system were seen consistently across studies, routes (oral &amp; inhalation) and species. In certain instances the effects are not described in very much detail, however, in other studies it is demonstrated that several elements of the blood system were affected at doses relevant for classification as STOT RE 2. RBC counts were reduced, though the reduction in Hb values generally did not exceed 20%. The stand-alone criteria seem not to be fulfilled, but in combination the observed effects demonstrate severe damage to the blood system. Especially the strong increases in Met-Haemoglobin reported in some studies are considered relevant.</p> <p>Also spleen and liver were affected (haemosiderosis, increased organ weights, extramedullary haematopoiesis) which indicates damage to erythrocytes, haemolysis and anaemia. Also the behavior was affected, labored breathing and reduced activity were observed, which together with a pale appearance are additional indications for anaemia. Altogether we consider the available data sufficient to support a classification as STOT RE 2, blood. With regard to mortality which was also seen in repeated dose toxicity studies we believe that this effect should be covered by classification for acute toxicity.</p>				
RAC's response				
<p>Thank you for your comment. RAC agrees that this substance should be classified with STOT RE 2.</p>				

**PUBLIC ATTACHMENTS**

1. P-I180 Reconcile MEKO CLH 20180710(2).pdf [Please refer to comment No. 2]