

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

White spirits

Substance name:	EC number	CAS number:
White spirit type 0	265-191-7	64742-88-7
White spirit type 1	265-185-4	64742-82-1
Stoddard solvent	232-489-3	8052-41-3
White spirit type 3	265-150-3	64742-48-9

Member State: Denmark

Dated: August 2014, Final version

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The Danish EPA has conducted a survey of all substances listed on the Danish List of Undesirable Substances (LOUS). Access to the surveys carried out so far can be found at the following link:

http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/

The survey on white spirits includes 3 oil-derived hydrocarbon substances: White spirit type 0, White spirit type 1 and Stoddard solvent. White spirits were included on LOUS because of concern for their potential for chronic effects on the central nervous system (the "painter's syndrome") after long term inhalation exposure. The results of the survey have been used as the main background information for this RMO. The survey carried out for white spirits provides an overview of the regulation, the use and the environmental and human health aspects of the substances.

An additional white spirit, White spirit type 3, is included in this RMO. This substance is used as an alternative to other white spirits. However, the Danish EPA is concerned that this substance has similar toxicological effects.

The current status of white spirits pertaining to relevant community legislation is summarised in Table 1 below.

Table 1. Relevant legislation pertaining to the manufacture and use of white spirits

Legal instrument	EU/national	Status of white spirits
REACH regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Three of the 4 substances are registered in the following tonnage ranges: White spirit type 0: 10,000-100,000 tonnes White spirit type 1: 1,000,000-10,000,000 tonnes White spirit type 3: 1,000,000 - 10,000,000 tonnes Stoddard solvent: registered, but not registered (<100 t)
CLP regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	EU harmonised classification is available for White spirit type 0, White spirit type 1, Stoddard solvent and White spirit type 3. The classification was recently amended (5th ATP) with STOT RE 1 for the 3 first mentioned substances, but not for White spirit type 3. Industry self-classification is reported to

Legal instrument	EU/national	Status of white spirits
		the ECHA C&L inventory database.
Directive on Chemicals Agents at Work	Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work and implementing directives 2000/39/EC, 2006/15/EC, 2009/161/EU	<p>The Scientific Committee on Occupational Exposure Limits (SCOEL) has proposed the following value as recommended occupational limit value for white spirits in 2007:</p> <p>20 ppm (116 mg/m³) as 8 h average level 50 ppm (290 mg/m³) as 15 min STEL level and attachment of Skin notation</p> <p>The OEL for white spirit is considered to apply to all complex hydrocarbon mixtures with their main compounds in the range from C₆ to C₁₂. This includes a.o. white spirits type 1 and 3 and Stoddard solvent.</p> <p>No indicative occupational exposure limit values (IOELS) for white spirit is part of the Commissions 3 lists of indicative occupational exposure limits values</p>
VOC Directive	DIRECTIVE 2004/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC.	The "VOC" directive that aim to avoid/reduce ozone formation potential of the VOCs in connection with photo-chemical reactions in the ambient air defines 12 subcategories for coating products applied to buildings and 5 subcategories for vehicle refinishing products for which limits are set with regard to the content of volatile organic compounds, VOC. The maximum VOC content has been set in the range of 30 - 840 g/l depending of the product.
Waste Framework Directive	Directive 2008/98/EC the European Parliament and of the Council of 19 November 2008 on waste	According to the Directive a concentration of 1% in waste at a concentration that triggers classification of a mixture according to the CLP Directive will render the waste hazardous (based on 5th ATP to CLP).

White spirit type 0, type 1 and type 3 as well as Stoddard solvent are all subjected to EU harmonised classification Asp. Tox; H304 (May be fatal if swallowed and enters airways).

STOT RE 1 H372 (Causes damage to the central nervous system through prolonged or repeated exposure) was added to the harmonised classification of White spirit type 0, White spirit type 1 and Stoddard solvent in the 5th ATP to CLP. The classification of White spirit type 3 was not amended.

Furthermore, White spirit type 1, type 3 and Stoddard solvent are classified with Carc.1B; H350 (May cause cancer) and Mut. 1B; H340 (May cause genetic effects), if the content of benzene in the substance is greater than 0.1 w/w%. However, the solvents are generally produced with lower levels of benzene and thus in practice the solvents on the market do not carry these classifications. Stoddard solvent type 3 contains a maximum of 1% w/w aromatic compounds, and thus may contain a lower amount of benzene than other white spirits with higher aromatic contents.

In addition, the most widely used self-classifications are:

- Flam. Liq. 3; H 226 (Flammable liquid and vapour)
- Eye Irrit. 2; H319 (Causes serious eye irritation)
- STOT SE 3; H336 (May cause drowsiness or dizziness)
- Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)

2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	X
Substance evaluation	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	X
National initiatives	X
No need for regulatory follow-up action	

Repeated exposure to white spirit may lead to risk of developing chronic neuropathy if not controlled. A SCOEL opinion on OEL setting for white spirit from 2007 is available. It could be considered by the Commission and the Member States to include the values proposed by SCOEL in a coming list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC. DG Employment has already been notified of this proposal by DG Environment.

There is concern that White spirit type 3 may have adverse effects to human health similar to the 3 white spirits already classified. Due to lack of specific data, this substance is not regulated e.g. through classification and labeling. However, as the substance is used in high tonnage, exposure may be significant, and a risk to human health cannot be discarded. Therefore, Denmark has filed white spirit type 3 for inclusion by ECHAs in its prioritization of substances that should undergo substance evaluation.

The consumer may be at risk when using white spirit containing products in non-ventilated confined spaces. Information to the consumer stressing risk mitigation measures may be considered at national level.