



致公司 (To) :	凤礼所有销售及相关客户	日期 (Date) :	2012/11/21
收件人 (Attn) :		方式 (Designation) :	E-mail or Fax
发件人 (From) :	窦静涛	部门 (Department) :	市场部
总页数 (Pages) :	1+2	附件 (Attachment) :	1
主题 (Subject) :	关于 Crodamol EO 变更有效期的通知	电话 (Telephone) :	010-87966828

此致：凤礼销售代表及最尊敬的客户

请查收英国 Croda 公司最新的变更通知。

从 2013 年 1 月 1 日起，Croda 将对其油酸乙酯 Crodamol EO 实施如下变更：

1、Notification of Change to Validity Period 即产品有效期的变更

Croda Europe Ltd Leek Site 禾大欧洲工厂 Leek 生产的 Crodamol EO 有效期变更为 2 年；

2、Notification of Packaging Change for those customers currently receiving plastic drums 即当前客户塑料包装桶的变更

- 1) Supply of material in lacquer-lined steel drums
内部涂层钢桶说明
- 2) Change of net weight from 190kg to 180kg (for SR Sesame Seed oil only)
净重变更为 180 公斤/桶 （限于超纯精制芝麻油）

·Intermediate (30°C±2°C/65% RH±5% RH) 阶段储存仓库条件

·Long-term (25°C±2°C/60% RH±5% RH) 长期储存仓库条件

内部涂层将履行 EU 规定的 EC1935/2004 可应用于食品的涂层标准，并将相关信息标注在桶的表面，详见附件内表格。

以下内容无任何变更：

·The process route 工艺路线

·The site of manufacture 生产地点

·The specification applied to the product 产品规格

3、附件变更信件原文，如有任何问题请随时联系我们。

北京凤礼精求商贸有限责任公司

2012 年 11 月 21 日星期三



CRODA

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Date: 19 Nov., 2012

Beijing Fengli Jingqiu Commerce and Trade Co., Ltd

Dear Sir / Madam,

We wish to notify you of the following changes to the following products manufactured at the Croda Europe Ltd Leek site and supplied to you. These changes will be effected from **01 January 2013**

1. Notification of Change to Validity Period

Existing stocks of material will be updated with the new validity period.

These changes are being implemented as part of a continuing improvement program which will provide increased benefits to the product supplied by Croda Europe Ltd Leek site.

The changes are summarised in the table below

Product Name	Product Code	Existing Validity Period	New Validity Period
Crodamol EO	RV06440	15 month retest	2 year expiry

2. Notification of Packaging Change for those Customers currently receiving plastic drums

We wish to notify you of a change to the packaging and drum weights applied to the products manufactured at the Croda Europe Ltd Leek site and supplied to you. This change will be effected from 01 January 2013 however existing stocks of material will be supplied in the current packaging. The specification for these drums is shown below in Table 1.

The changes are:

1. Supply of material in lacquer-lined steel drums
2. Change of nett weight from 190kg to 180kg (for SR Sesame Seed oil only)

Both these changes are being implemented as part of a continuing improvement program which will provide increased benefits to the product supplied by Croda Europe Ltd Leek site.

These changes are supported by data obtained from an on-going stability study carried out in lacquer-lined steel drums in accordance with the ICH Harmonised Tripartite Guideline "*Stability Testing of New Drug Substances and Products Q1A(R2)*".

The interim data generated thus far demonstrates product packaged in lacquer-lined steel drums gives equivalent stability compared with existing packaging based on results obtained under Accelerated Conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\% \text{ RH}$).

Ongoing stability studies are also being carried out on the product range at the following conditions

- Intermediate ($30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \text{ RH} \pm 5\% \text{ RH}$)
- Long-Term ($25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $60\% \text{ RH} \pm 5\% \text{ RH}$)

As the stability trial progresses and then concludes it may be possible that the period of validity applied to your product may change. If this is the case we will inform you.

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The new packaging has undergone a full technical and quality review and has been confirmed as a suitable replacement.

The lacquer lining present in these drums is in accordance with EU regulation (EC) 1935/2004 on the use of coatings intended to come into contact with foodstuffs.

The new packaging details are summarised in the table below along with appropriate comparison to existing drums:

Parameter	New Drum	Existing Drum
Empty Weight	14.9 kg	8.40 – 8.80 kg
Body Material	Steel, Spiral-seamed, 2 Body beads.	HDPE
Lining	Lacquered RDL 50/1	None
Height	844 mm \pm 3mm	935 \pm 5mm
Diameter	582 mm	580 \pm 5mm
Nominal Capacity	210 litres	220 litres
Colour (Body)	Blue RAL 5010	Blue
Colour (Top / Lid)	Blue RAL 5010	Blue
Colour (Bottom)	Blue RAL 5010	Blue
Thickness (Body)	0.8 mm minimum	2.8 mm
Thickness (Ends)	1.0 mm minimum	2.8 mm
Head	Tight	Tight
Closure Type	2" & 3/4" Tri-Sure Non-vented Pre-Lacquered Bungs with Black Nitrile Washers	2 x 2" Tri-Sure Non-vented Pre-Lacquered Bungs with Black Nitrile Washers
UN Certificate	U1A1/X/250/**	1H1/Y1.9/200
Food Contact Regulations	Complies	Complies
Heavy Metals Requirements	Complies	Complies

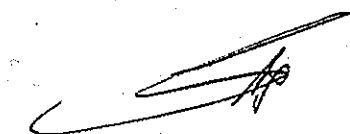
I can confirm there will be NO change to any of the following parameters:

- The process route
- The site of manufacture
- The specification applied to the product

Please note that the minimum remaining validity period of material supplied to you will not change as result of this change

If you have any questions or require any further information please contact your local Sales Representative.

Yours Sincerely,



Managing Director
Croda Hong Kong Co Ltd.
Croda China Trading Co Ltd.
Croda Shanghai Trading Co Ltd.

Crodamol EO



注射级油酸乙酯 EP/NF

Crodamol EO 系油酸乙酯,符合欧洲药典和 NF 标准. 油酸乙酯主要用途是肌肉注射等针剂产品的增溶剂. 由于油酸乙酯比其他非水性增溶剂的黏度低, 所以它经常用来增溶油溶性的药物,能迅速被人体组织吸收. 油酸乙酯是非常好的激素载体,比较植物油油酸乙酯能促进激素的作用.

Crodamol EO 有以下功能的优点,在许多药物系统都有各种优良表现:



- 油溶性药物载体
- 能溶解和分散油溶性药物
- 非封闭性的润肤剂
- 优良的铺展性
- 黏度低

应用领域:

肌肉和皮下注射

- 能溶解激素和固醇类药物, 可用于肌肉注射
- 能溶解一些皮下给药胶囊的药物
-

口服

- 能溶解油溶性药物
- 能作胶囊型安慰剂 placebo

外用药膏

- 能用在外用搽剂和膏霜
- 透皮给药系统
- 对皮肤滋润效果好,铺展性强

Crodamol EO 是非常优秀的稀释剂和载体,大大优于传统的矿物油和植物油有. 除了它优秀的溶解能力, Crodamol EO 化学性能稳定,不会和化学性质敏感的药物反应. 另外, Crodamol EO 是优秀的非封闭型的润肤油脂,在皮肤上的铺展性好. 在众多 Croda 的润肤剂中, Crodamol EO 的皮肤铺展性非常高¹, 能促进外用药膏的铺

展性和润肤效果. Crodamol EO 因此既能使外用药膏膏体美观细腻,又能给患者舒适的滋润感觉.

理化指标

25°C 时的外观	淡黄色液体
凝固点	≈ -32°C
平均运动黏度 (at 25°C)	6.6 mm ² s
平均运动黏度 (at 37°C)	5.0 mm ² s
平均运动黏度 (at 4°C)	11.2 mPas (240 rpm, SC4-21)
皮肤铺展系数 ²	8.5

国际权威认证情况:

- 在“FDA 非活性原料指南”的经皮给药辅料有关章节有介绍
- 在英国注册的注射制剂中有使用
- 在 21 CFR 172.515 合成香料和辅料中有注册

储存要领

Crodamol EO 应该在阴凉,干燥的密封容器中储存,远离光线

健康和安全要领

Crodamol EO 是无毒,对眼睛和皮肤没有刺激性. Crodamol EO 是运用在皮下和肌肉注射产品中.

参考书目:

1. AJ Spiegel and MM Noseworthy, 非水性注射溶剂的使用, 制药科学杂志, Vol 52, 1963 年 10 月

The Skin Spreading Factor represents the ratio of the final area of coverage from the emollient divided by the initial area over which the emollient was applied. Further details are available on request.

Non-warranty

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